HEARING V ON YEAR 2000 READINESS IN THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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HEARING V ON YEAR 2000 READINESS IN THE DEPARTMENT OF VETERANS AFFAIRS

THURSDAY, OCTOBER 28, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to call, at 10:04 a.m., in room 334, Cannon House Office Building; Honorable Terry Everett (chairman of the subcommittee) presiding.

Representatives present: Everett, Brown, and Udall.

OPENING STATEMENT OF CHAIRMAN EVERETT

Mr. EVERETT. The hearing will come to order.

Let me say at the outset I will try to get through my statements and questions. I had some drops put in my eyes and I can't see the script that well.

Good morning. The hearing will examine the final preparations of the Department of Veterans Affairs for the year 2000 computer compliance.

This is our fifth hearing on Y2K. Today we are 63 days from year 2000. We will hear testimony from the GAO, the VA, and the FDA on how prepared the VA and FDA will be on January 1, 2000.

Today we will stress the VA's readiness to provide uninterrupted veterans benefits, veterans compensation and pension checks, safe medical care, and prescriptions when the moment arises.

I cannot overstress the importance of the VA being as fully prepared as possible. No detail can be left unanticipated and unaddressed. There cannot be any attitude of "this won't happen." Contingency plans cannot merely accept verbal agreements or assurances from suppliers for such things as emergency generators, fuel supplies, alternative water sources, and food shipments. Everything must be narrowed down to the greatest possible extent.

When the VA facilities run Y2K drills and exercises, they need to seriously address and correct identified deficiencies. Veterans depend on the professionalism, thoroughness and keen attention to detail of the VA as the department completes its Y2K preparation.

We have a lot to cover. Now I would like to recognize our ranking Democrat, Corrine Brown.

OPENING STATEMENT OF HON. CORRINE BROWN

Ms. BROWN. Thank you, Mr. Chairman. Well, here we are again, Mr. Chairman, trying to reassure America's veterans and their

families that VA hospitals will operate normally on New Year's morning and that all checks will be delivered on time.

Today it will be nice to hear VA report on how it is really ready to roll over into the year 2000 and how it received two "A's" last month from the House Oversight Committee that was grading Y2K government efforts.

It also will be nice to hear the Food and Drug Administration say how much confidence it has that essential medical supplies will be available, that medical devices will function as intended, and that there will be a safe and adequate supply of drugs available.

I am concerned, however, Mr. Chairman, that all of today's nice talk will be meaningless if VA has to walk its walk in a community that is shut down by a massive power outage or in a town where the water supply has been cut off for a long time.

I am sure VA will tell us each of its facilities is planning on such contingencies. The real answer to how well VA's decentralized health care system has done its local planning and will not come today, but at midnight on January 1.

I appreciate the dedication of those VA employees who plan to give up their New Year's holiday to ensure that America's hospitalized veterans might celebrate the new millennium in comfort and safety. To the Department of Veterans Affairs and all of those it serves, I wish you a smooth and uneventful new year.

Mr. Chairman, I know that GAO has some continuing concerns. I want to say for the record how much I appreciate GAO's diligence in keeping VA and FDA's feet to the fire over the past 2 years.

VA's Office of Inspector General also has been active in assisting the department get ready for the new year rollover.

Inspector General Griffin is not testifying here today, Mr. Chairman, but I would ask that his letter to me dated October 25, 1999, outlining the work of his office in this matter be made part of the record.

Mr. EVERETT. Without objection.

(The letter follows:)

DEPARTMENT OF VETERANS AFFAIRS
INSPECTOR GENERAL
WASHINGTON DC 20420

OCT 25 1999

The Honorable Corrine Brown
Ranking Democratic Member,
Subcommittee on Oversight and
Investigations, Committee on Veterans' Affairs
House of Representatives
Washington, DC 20515

Dear Congresswoman Brown:

In response to your request, we are providing a summary of our review involving the Department of Veterans Affairs (VA) efforts to address Year 2000 (Y2K) issues and become Y2K compliant. As we discussed in our April 1999 testimony before the Subcommittee, the Office of Inspector General (OIG) has been involved with review and oversight of the VA's Y2K implementation efforts since 1997. Given the importance of correcting Y2K problems in VA computer systems and ensuring that veterans receive uninterrupted services, we are continuing to provide the Department with input and support as the millennium approaches.

Our review work has shown that VA's Y2K efforts were well organized and focused on those mission critical systems that must be compliant to ensure that veterans receive uninterrupted services. VA has reported that it has successfully completed implementation of all mission critical systems and is now engaged in completion of necessary contingency planning actions leading up to and including the "Day One Rollover".

Our focus on Y2K issues has been to identify areas where VA's implementation efforts could be strengthened and to respond to any Department requests for assistance. During 1999, our Y2K related efforts have included: (1) issuance of an audit report on VA's Y2K Implementation Effort in June 1999, (2) issuance of an Advisory on the Status of Selected Y2K activities in VA in September 1999, and (3) completion of site visits to selected VA facilities to further assess Y2K implementation actions.

On June 10, we issued an audit report on VA's Y2K Implementation effort. During our April 15 testimony before the Subcommittee, we discussed the audit results that identified a number of key actions that could help make VA's Y2K efforts more successful, reduce operating costs, and ensure continuity of operations beyond the millennium. The report recommended that the Acting Assistant Secretary for

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Information and Technology assure that necessary corrective actions be accomplished to address the Y2K weakness identified. Specifically, we recommended:

- Completing contacts with Electronic Data Interchange trading partners (vendors) and Value Added Networks (VAN) to determine their Y2K compliance to assure continued electronic processing of transactions involving VA purchases.

- Establishing a 'cutoff' date for VA facilities to take biomedical devices of unknown Y2K status out-of-service and complete plans for replacement so that necessary procurement lead time is available and replacement costs can be identified as soon as possible.

- Completing corrective actions that were initiated during the course of the audit in response to our Interim Advisory Letters to address other Y2K weaknesses.

The Acting Assistant Secretary for Information and Technology concurred with the audit findings and recommendations presented in the report and provided appropriate implementation actions. Also, in response to our findings the Acting Assistant Secretary requested additional assistance to conduct follow-up site visits to VA facilities to further assess reported Y2K implementation actions.

In response to the Acting Assistant Secretary's request, we conducted follow-up meetings with him and the VA Y2K Project Manager, the Veterans Health Administration (VHA) Y2K Project Manager, and the Veterans Benefits Administration (VBA) Project Manager. These meetings identified some continuing areas of concern involving VA field facility Y2K implementation efforts.

On September 15, we provided the Acting Assistant Secretary for Information Technology with an Advisory on the Status of Y2K Activities in VA. The Advisory alerted him to some areas of concern that we identified during our meetings with VA Y2K officials, and discussed additional review work that we planned to complete.

We advised that while renovation of VA mission critical systems had been completed, our meetings with VA Y2K officials identified some concerns regarding the completion of other actions involving field level Y2K implementation efforts in both the Veterans Health Administration (VHA) and the Veterans Benefits Administration (VBA). These concerns have developed due to the decentralized nature of required Y2K implementation actions that make it difficult for Department officials to efficiently monitor the compliance process. The following areas of concern were identified:

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- VHA issued guidance to field stations on the completion of a Customized Local Contingency Plan. Contractor Personnel and VA employees knowledgeable in contingency plans have reviewed all of the plans completed by the field stations. However, some of the plans consisted of only copies of the guide sent out by the Y2K project management staff, and were not customized to address individual facility planning needs.

- VHA has issued requirements that all biomedical devices in veterans' homes be assessed. Home Based Health Care Services and Prosthetics Services have been tasked with identifying and assessing devices located outside the medical centers. The VHA project management staff has not required any reports on the status of this initiative. As a result, VHA staff is depending on the local facility to 'follow through' with the plan.

- VHA directives require that Medical Center Directors certify that any biomedical device evaluated non-compliant or unknown has been assessed. If they intend to continue to use a device beyond December 31, 1999, the Director must certify that he/she has had the risk evaluated by a committee and must describe the contingency plan or why the non-compliance is considered a non-factor. For devices assessed as conditionally compliant, the same certification was required by September 1. The VHA Y2K staff is not routinely reviewing or controlling these certifications.

- VHA Project Management staff indicated that they are concerned about the results of the mandated Emergency Electrical Power tests that were to be conducted by August 31. This test required that all facilities operate with only the emergency generators while completely disconnected from local power providers. The Y2K staff is concerned that the test itself was poorly conducted or not run at all.

- VBA has required certifications from the General Services Administration regarding the compliance of buildings. We have been advised that some of the buildings are still not Y2K compliant.

- VBA has not gotten assurance that outbased activities are properly prepared for infrastructure failures. With the opening of outbased claims processing activities on military bases, kiosks in mall for veterans to begin the claims process, and access to veterans' claim data by Service organization, infrastructure support issues become more immediate. The VBA Y2K Project Manager indicated that she had no knowledge as to whether or not anyone had verified the infrastructure support issues for those remote sites not located on VA stations. This would include outbased veterans assistance centers, outbased field examiners, and others.

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Because of current resource constraints, we advised the Acting Assistant Secretary that we were not able to complete a follow-up audit. As an alternative, we are completing information surveys on selected Y2K areas of concern to gather information on the status of implementation actions during site visits to VA Medical Centers (VAMC) and Regional Offices (RO) as part of other ongoing OIG projects. The sites selected for conduct of the survey were those to be visited by OIG staff conducting the Congressionally mandated Audit of Department of Veterans Affairs Consolidated Financial Statements for Fiscal Years 1999 and 1998 and Combined Assessment Program reviews at VAMCs. The eight sites selected for review included:

VAMC Albuquerque, NM	VARO Philadelphia, PA
VAMC Ann Arbor, MI	VAMC Portland, OR
VAMC Durham, NC	VAMC Syracuse, NY
VAMC Philadelphia, PA	VAMC Wichita, KS

To date, we have completed information surveys at VAMC Ann Arbor, MI and VAMC and VARO Philadelphia, PA. These surveys have found that Y2K implementation actions have been completed in the areas of concern that we reviewed involving medical devices, utility systems, and preparedness. We expect to complete the remaining surveys in the next 30 days.

We appreciate the opportunity to provide input on our review and oversight of VA's Y2K implementation efforts. A copy of this letter was also provided to the Chairman, Subcommittee on Oversight and Investigations.

Sincerely,

RICHARD J. GRIFFIN

Ms. BROWN. A June 1999 IG audit found that VA's Y2K efforts were well organized and focused on those mission critical systems that would ensure interrupted services.

In August 1999, after concurring with the audit's finding, the VA provided appropriate action to implement its recommendations.

Mr. Chairman, I request that my entire statement be placed in the record that we move on with the hearing.

Mr. EVERETT. Without objection. Thank you very much.

[The prepared statement of Congresswoman Brown appears on p. 25.]

Mr. EVERETT. I will now introduce panel 1, Joel Willemssen, Director, Civil Agencies Information Systems, Accounting and Information Management Division of the GAO, and ask him to introduce his panel.

Before you begin, Mr. Willemssen, again I want to commend and thank you on behalf of all Americans, especially America's veterans, for you and your staff's hard work in watchdogging the VA's Y2K efforts. I know a lot of hard work, many hours and weekends were spent by you and your staff over the last 3 years to evaluate and produce this testimony. You have performed an invaluable public service to this country and to this country's veterans.

I would also like to associate myself with the remarks of Ms. Brown on the contribution made by the VA's Inspector General.

If you will now introduce your staff and proceed, I would appreciate it.

STATEMENT OF JOEL C. WILLEMSSEN, DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY HELEN LEW, ASSISTANT DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS

Mr. WILLEMSSEN. Thank you, Mr. Chairman, Ranking Member Brown. Thank you for inviting GAO to testify today. Accompanying me is Helen Lew, Assistant Director.

As requested, I will briefly summarize our statement.

Overall, VA continues to make progress on Y2K. For example, both VBA and VHA have completed key testing of mission critical systems.

Second, VHA's consolidated mail outpatient pharmacies have developed business continuity and contingency plans to address any Y2K-induced disruptions that may occur.

In addition, VA has established a moratorium on software changes to help ensure that Y2K readiness is maintained through the rollover period.

Further, VA has developed a day one strategy, laying out its plans and procedures for the late December, early January time period.

VA is to be commended for this progress and for reducing the risk of Y2K disrupting service to our veterans.

Mr. Chairman, your subcommittee has been instrumental in this progress. Dating back to 1996, long before many knew what Y2K was, your subcommittee was providing oversight of VA's Y2K efforts, oversight that has led to substantial improvements in VA's program.

Even with these improvements and the progress that has been made, VA's job is not done. The department must still complete numerous tasks in the limited time remaining to further reduce the risk of Y2K-induced disruptions.

For example, as of October 22 only five of VBA's 58 regional offices had completed testing of their business continuity and contingency plans.

Second, VHA acknowledges that the reports used to measure medical facilities' progress in implementing Y2K compliant systems are inaccurate. It is critical that these reports be accurate so that any problem areas can be identified and resolved.

Third, we believe VHA needs to reassess its position of not testing any biomedical equipment items. Our review of manufacturers' web sites found at least 30 companies that encourage users to test certain biomedical equipment, and 15 of these provided information such as testing instructions. For these types of instances in which the manufacturer is encouraging users to test, VHA should reconsider its current policy of not testing.

Fourth, we believe that VHA needs to continue to follow up with pharmaceutical and medical surgical firms on their compliance status and make this information available on VA's web site.

Next, turning briefly to FDA, it too has made progress by continuing to make compliance information on biomedical equipment available to users through its clearinghouse. FDA has also recently addressed our concern about the lack of independent verification of critical care and life support biomedical equipment by reviewing a sample of manufacturers' Y2K activities.

In the limited time remaining FDA still needs to finalize its report on this and make the results available to the public.

FDA is also conducting surveys to determine the Y2K readiness of pharmaceutical, biological and consumable medical product manufacturers. FDA needs to follow through on its plans to publicize the results of its surveys in all of these areas.

That concludes a brief summary of my statement, and I would be pleased to address any questions you may have. Thank you.

[The prepared statement of Mr. Willemssen appears on p. 27.]

Mr. EVERETT. Thank you very much. With the agreement of my ranking member, I will hold myself to 5 minutes and you'll take 5 minutes, and then we will have another round.

Chairman Horn's Subcommittee on Government Management and Information Technology of the Committee on Government Reform recently gave grades on Y2K preparedness. The VA was one of only three agencies to receive a grade of "A". Of these three, VA is by far the largest and the most complex. Does GAO agree with this assessment of the VA?

Mr. WILLEMSSEN. Chairman Horn puts his quarterly grades together based on the quarterly reports submitted by the 24 departments and agencies, and we assist him in that endeavor. Based on the criteria he uses, which is self-reported information, we would concur with his assessment. However, if an "A" implies that VA has completed its work on Y2K, then we would not concur with that assessment based on the independent work that we have done in identifying some additional tasks that still need to be completed in the remaining weeks.

Mr. EVERETT. I do not want to interpret Chairman Horn's grading system, but is his grading system based on A-plus being perfect, or is it in relationship to where the other agencies are?

Mr. WILLEMSSEN. He has often said he does not grade on the curve. The initial baseline for his grade is the percentage of mission critical systems at any given point in time that are considered compliant. Then he uses additional criteria in areas such as embedded chips, telecommunications, business continuity and contingency plans. Based on what the agencies have said on those areas and how much progress they have made, he then adjusts the grade.

I think it is worthwhile noting that over time the overall government-wide grade, along with VA's grade, has escalated as Y2K has become a much higher priority to top management, not only at VA, but government-wide.

Mr. EVERETT. VHA estimates over 95 percent of its devices are compliant; 3 or 4 percent require an upgrade; the remainder are simply non-compliant. VA appears fairly confident with its Y2K biomedical preparation. Is GAO comfortable with such an assessment?

Mr. WILLEMSSEN. We have two caveats to that overall assessment. One is to keep in mind that the information provided is based on what biomedical equipment manufacturers are stating in their compliance statements. That is why we are very reassured that for critical care and life support items FDA is following up and doing some independent work in that regard.

Second, I briefly mentioned that there are inaccuracies in some of VA's reports from their medical facilities. That is another caveat in terms of our comfort level in making sure that those reports are accurate so that top management at VA knows exactly where they stand.

Mr. EVERETT. In your overall review of VHA medical facilities did you find any general deficiencies? What about critical ones related to particular facilities? How about planning associated with critical delivery like patient care, intensive care, and operating rooms?

Mr. WILLEMSSEN. First, overall we again have seen tremendous progress in VHA's efforts with their medical facilities. In particular, they have done some good work in getting the ball rolling in the business continuity and contingency planning area. However, in looking at some of those contingency plans, we did note that the necessary detail in laying out exactly the tasks to be done, especially in the late December, early January time frame, were not always discussed. We know that VHA is following up on that and planning to address that.

In addition, I believe a couple of plans did not give a lot of detail in terms of completing the templates that were required as part of the contingency plans.

Mr. EVERETT. VA reported to the GAO 18,000 non-compliant biomedical devices. Could GAO determine VA's status on these assessments of renovations of these devices?

Mr. WILLEMSSEN. From a universal perspective, no, we could not. My caveat on that is that some of the reports from the medical facilities were not totally accurate. For example, we saw some cases of percentages exceeding 100 percent. With those kind of inaccura-

cies we couldn't absolutely be certain that the data there was good enough to satisfy us, and also VHA acknowledged some of those data deficiencies and is actively following up on them now.

Mr. EVERETT. Has VA tested biomedical devices that are interdependent on other pieces of equipment that may experience Y2K problems? Does VA know how many of these devices must operate in conjunction with others?

Mr. WILLEMSSEN. VHA's position is for the piece of equipment in and of itself it does not want to independently test. However, when it works with an interface with another piece of equipment or, let's say, a personal computer, they do plan to test that. I do not have at my disposal all the results of those tests.

One thing that we would like to see VHA consider, though, is for those biomedical equipment items where the manufacturer has encouraged users to test and in some cases actually laid out the testing instructions, we think VHA needs to reassess its position of not testing any equipment items.

Mr. EVERETT. Thank you. Ms. Brown.

Ms. BROWN. Thank you, Mr. Chairman.

GAO has done a lot of heavy lifting in the area of Y2K readiness over the last 3 years. I personally appreciate the service that you provided this subcommittee and your pushing VA and FDA in a defined direction toward the Y2K finish line. As January 1 nears, how would you summarize the lessons learned from this complex, high tech exercise, and what would you say were the most useful byproducts of our joint efforts?

Mr. WILLEMSSEN. Among the most key of the lessons learned through this exercise is that VA top management now very well understands the criticality of information technology. In this day and age, it is very difficult to delivery benefits and services without the information technology that we are so reliant on. I think Y2K has assisted the department in making it aware of technology's paramount importance.

Secondly, we hope that some of the best practices that VA has adopted through this exercise over the last few years can be taken and used on some of the other management areas within information technology at the department. VA has occasionally had difficulties managing other aspects of its information technology resources. To the extent that they can use some of the lessons from Y2K and better manage the entire information technology environment, I think that would be very beneficial not only for the department, but for our veterans.

Ms. BROWN. Being a former teacher myself, on a scale of one to ten, how would you rate VA?

Mr. WILLEMSSEN. I guess it would be difficult to give an exact number, but at this point in time I would give them a much higher number than I would have when we initially started our work a couple of years ago. I would not give them a ten, because a ten implies that everything is done. As I have testified, everything is not yet done. But I would definitely give them a fairly high number given the kind of progress they have made, the kind of priority that Y2K has been in the department for sometime, and the responsiveness that they have had to the recommendations that we have offered to them.

Ms. BROWN. In comparison to the other agencies?

Mr. WILLEMSSEN. VA is among the better agencies of those that we have reviewed. As the Chairman mentioned in one of his early questions, VA faces a tremendous amount of complexity that several other departments and agencies do not, especially when it comes to all the medical facilities. They run a much larger risk of disruptions, especially during the early January rollover period, because of the massive environment that they are responsible for and the criticality of information technology.

Ms. BROWN. Thank you.

Mr. Chairman, I yield back.

Mr. EVERETT. Mr. Udall.

Mr. UDALL. Thank you, Mr. Chairman. I also want to thank the two panelists from the GAO for being here with us today.

Except for the issue of independent testing of medical devices that have been certified as Y2K compliant by the manufacturer, you note that the VA has been very responsive to your recommendations. What are the top five things that the VA needs to do right now? Do they still have time to do them, and what would be the consequences of their not doing them?

Mr. WILLEMSSEN. I think, one, they do have time to address the areas that I will mention in terms of the top five.

First, on business continuity and contingency plans, they need to make sure that those plans are thoroughly tested both at their regional offices and at their medical facilities.

Secondly, more detail on the medical facilities and their contingency plans is needed. We pointed out some of the excellent work that has been done in terms of looking at what would happen at those facilities if they lost power. We think they could also benefit greatly by looking at the risk of losing other things such as water or gas and what those facilities would do as a backup in that situation.

Third, some of the consolidated mail outpatient pharmacies still need to make sure that their business continuity plans are not only tested but they are integrated with the medical facilities.

Fourth, we would like to see VHA follow through with the firms in the surveys that they have performed in the pharmaceutical, biologics and consumables area. They have done some excellent work, obtained some data, but again we do not think the job is done. It is important to follow up with those companies who said they were going to be compliant by certain dates and make sure that indeed they are done.

Last, I would still want to emphasize in the biomedical equipment area the need to take a second look at those items where manufacturers are saying "we think you should test." I think VHA needs to reassess its decision not to test anything.

Mr. UDALL. Do they understand what kind of testing you are talking about as far as medical equipment?

Mr. WILLEMSSEN. Yes. In several cases the manufacturer actually lays out the test protocols and instructions. To be fair to VHA, we are a little late coming to this game too, because we initially shared VA's concern about going in and testing these devices and possibly doing harm to them. But then we started looking into this a little bit more.

My eyes were especially opened at a congressional field hearing in San Jose in August where representatives from Hewlett-Packard testified and said they strongly encourage users to test because of the way that the systems may be set up. That is when we started doing more work and looking at manufacturers' web sites, and we identified many manufacturers actually encouraging that testing.

Frankly, I think over a period of time the ratio has changed. I think more and more manufacturers are seeing the benefit of getting users involved in the testing rather than just relying on their own certifications.

Mr. UDALL. Thank you very much. I yield back my time.

Mr. EVERETT. Thank you.

Let me again thank you very much for your testimony here today and the good work you have done for this country and its veterans in what we all thought was going to be a really, really tough road. I think all over the nation many people still are sort of worried about it. Thank you very much.

Mr. WILLEMSSEN. Thank you, Mr. Chairman.

Mr. EVERETT. I would like to introduce Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation for the Food and Drug Administration.

Mr. Hubbard, if you would introduce those members of the panel with you, and after that, if you would proceed with your opening statement, I would appreciate it.

STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY THOMAS B. SHOPE, SPECIAL ASSISTANT TO THE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, AND MARK GOLDBERGER

Mr. HUBBARD. Mr. Chairman, I am joined here by Dr. Mark Goldberger, a drug expert and Y2K coordinator for pharmaceuticals at the FDA. To my left is Dr. Tom Shope, a medical device expert and our Y2K coordinator for medical devices.

We have a written statement for the record. I will say just a few opening remarks, if I may.

Mr. EVERETT. Without objection.

Mr. HUBBARD. When we were here in the spring the committee had concerns that the VA and other hospitals might have device failures that could harm veterans and other patients, and also concerns that the nation's veterans and other patients might not have access to needed pharmaceuticals and medical supplies. So let me tell you today what we have done since that time to address those issues.

For medical devices, the problem was focused on devices that may cause harm if a device failed because of a date-dependent problem. We identified the manufacturers of devices that are potentially high risk if a Y2K failure should occur. That number turned out to be just over 300 manufacturers, representing about 90 types of computer controlled devices.

We then launched intensive audits of a sample of 80 of those 300 manufacturers. I am pleased to tell you today, Mr. Chairman, that

none of the audits raised significant concerns about failure of manufacturers to properly address computerization of their devices.

For drugs and medical supplies, working under the leadership of the VHA, we have surveyed the industry to ask if their manufacturing processes are Y2K compliant. This was done both to gather information about these products, that they would be safely made, and to be able to assure the public that their prescriptions can and will be filled after January 1.

We followed the survey with comprehensive audits of a list of priority firms. These are firms that are the only manufacturer of a particularly important drug or so-called orphan drug and the top 200 selling prescription drugs. Again, I am pleased to inform you that for those priority firms the vast majority, over 95 percent, are Y2K compliant, and that none of these manufacturers are expected to experience problems that would deprive patients of critically needed drugs and medical supplies at the beginning of the year.

We have also done a number of other things to help with the situation. We have done outreach to hospitals to make sure that they understand that they should avail themselves of the information, particularly on medical devices, that the fix is by and large there.

I think you will hear later that the VA has done a great job and has availed themselves of information. There is some information from GAO and others that perhaps some hospital systems have not done that. Although that is not FDA's responsibility, I do believe others have raised that concern. Clearly the information is out there from the manufacturers on the FDA web site or on other manufacturers' web sites about what devices are compliant and what are not and how to get the fixes for those that are not.

We have also done a number of things to assure the public about this through our 800 number, our web site, various brochures and articles and other things to get the word out that patients need not worry that these products will not be available.

And we have set up emergency operations and day one operations at FDA which will be manned 24 hours beginning next month. That will be available. If any issues or any problems appear, we will have teams of medical experts and engineers and others ready to go out and talk to companies or hospitals or anyone else that may give us information about a problem. We hope that doesn't happen, but we will do that.

I would also like to say the industry, Mr. Chairman, has responded appropriately to this challenge and they have invested the resources and the time to make their systems compliant, and the vast majority of companies have been very responsible in this area, in our opinion.

In conclusion, Mr. Chairman, we have attempted to do a graphic representation of our findings. As you can see from this sample to my left, if the firms that we have surveyed and audited came in about a third, a third, a third—ready, possible problems, or clearly a problem—we would see a chart that looks something like this with a third red, a third green, and a third yellow, green of course being ready, and red of course being a problem.

Let me tell you how the real results came out.

For the potential high risk devices, those that if they fail because of a date-related problem would cause risk to humans, we have a

wonderful response rate. Based on those that we have audited of those priority firms, 100 percent are ready.

For the consumable medical supplies, things like blood bags and tubing and hemodialysis filters, the things that hospitals need every day, we again have found 100 percent readiness. We have a few questions, but we have colored them in green because we in fact do believe they are ready, and these questions that we have are very minor.

For pharmaceuticals we have a very good record. We have only found one firm that we could categorize as a yellow, as having some issues, and we are working with that firm to make sure that those are not indeed problems.

Lastly, biologicals, things like vaccines and blood banks. We also have a very good report.

In summary, Mr. Chairman, across the industry that we regulate we believe that the signals are all go, that the industry has done what needs to be done, and there will not be problems. We will of course continue to monitor and make sure that this is in fact the case come January 1, but we are very optimistic.

With that, Mr. Chairman, I will conclude my remarks and be happy to take questions.

[The prepared statement of Mr. Hubbard appears on p. 79.]

Mr. EVERETT. Thank you very much. Mr. Hubbard, FDA conducted a survey of manufacturers for potentially high risk devices. Of the 803 manufacturers, 325 were randomly selected. Of these, 26 declined to participate and 4 did not respond. Are the names of the non-participants and the non-respondents public?

Mr. HUBBARD. We have not made them public. Under the Y2K Readiness and Disclosure Act, we have attempted to keep specific information about firms confidential. These firms that have not been audited are a range of firms, some that were simply busy trying to get their work done or were being merged with another company or had recently been inspected by the FDA. We don't think any are a problem with the possible exception of one, a blood transfusion software manufacturer in a foreign country that we intend to look very closely at.

We have not put their names out in the public for fear that it would provide a connotation that there is a problem with these firms that we don't believe exists. However, if the committee would like more detailed discussions about who they are, we would be glad to do that with the committee.

Mr. EVERETT. I would like more detail. How can you be so sure that there are no problems if they didn't respond?

Mr. HUBBARD. Let me ask Dr. Shope to elaborate.

Dr. SHOPE. I think there are no absolute certainties due to a lack of response, but we have looked at not only the firm and the fact they didn't respond, but what kind of products they make and what could be the impact of that type of product having a problem. By and large these firms do not make the kind of products whose failure would be an immediately critical problem. The firms have reported for their products their date functionality or dependencies, and many of them don't have any date functionality in their products.

I think we have a fair level of confidence that the firms, even the ones we haven't audited, are not making the kind of products that would present real issues because of their date functionality.

Mr. EVERETT. Doctor, that begs the question. Why wouldn't they respond?

Dr. SHOPE. I think for the firms there are a number of valid reasons. This is a very intensive effort. It involves probably 4 or 5 days of the firm, several of their top IT or product development specialists. It is a big imposition on a firm to undergo an FDA audit. This was strictly a voluntary activity. We had to express it to the firms as voluntary. That was the condition under which we did it.

Many of the smaller firms may have a number of things going on that would mean it was not opportune for them at the time we needed to actually conduct the survey. Several of them had said not right now, but come back in a month and we will be glad to do it. We, of course, had the goal of getting the survey done promptly. That was one of the reasons.

There is no suspicion that the firms are attempting to hide something.

Mr. EVERETT. You are a regulatory agency. Why aren't they responsive to you?

Mr. HUBBARD. Mr. Chairman, these audits were done voluntarily by contractors to FDA. They were not done by FDA investigators. If we believe there is any issue of safety or any concerns, and this one foreign blood transfusion software firm I mentioned may be one like that, we can send in an FDA investigator who can compel entry and ask these questions. We have not seen the need to do that yet, but we clearly can and will do that if we believe there is any risk to human health from these products.

Mr. EVERETT. For the record, this chairman would like to see those names listed.

Mr. HUBBARD. We will be glad to talk to the committee in more detail about those.

Mr. EVERETT. According to GAO testimony, FDA was supposed to submit the final report to HHS by 1 October. It has not occurred. Further, there is no revised deadline. When will this report be submitted to HHS? And I would like to know when this information will be made available to the public.

Mr. HUBBARD. There were delays that I will characterize as about a 2-week or so delay because many of the audits were being done in August when the key people were on vacation, and there were other difficulties. But we believe we will have a final report on this out by the first of November.

Mr. EVERETT. I understand GAO's testimony has given highest priority to 225 firms that produce devices that are only manufactured by a handful of these firms as well as 57 manufacturers that are sole source suppliers. According to an FDA senior associate commissioner, to date 197 of the high priority firms have responded and 48 of the 57 sole source firms have responded. As of October 25, 1999, FDA had not responded to our request as to whether it plans to make a detailed survey and audit results from consumer medical product manufacturers available to the public. When do you plan to make these results public?

Dr. SHOPE. We are currently working on a report that summarizes the results of our survey of the manufacturers of essential medical supplies, which is what you were referring to there. The 225 firms that are one of the few makers of a product or the 57 that are the sole source manufacturers of an essential supply. The report will describe an assessment of essential medical devices manufacturers and their manufacturing capability, not that they are computerized products that may have problems. It is the manufacturing process and the preparation to continue to deliver supplies that is being addressed.

We have a very high response rate from this survey. The remaining activity that we are doing right now is continuing to follow up with audits by telephone and in a few cases on-site audits with our contractor to verify the results of the paper survey that we got from manufacturers. We are currently drafting our report. The results, I think, are good.

The manufacturers have done a good job of planning for and developing contingency plans. Over 80 percent of the firms are telling us that they are going to be ready by this time of the year. The remainder are indicating that they will be ready by December 31. There are a few firms that we haven't heard from. We are currently looking at who those firms are, what kind of products they make, and are they really essential supplies, and if there are any firms that remain on the list that need action, we will follow up with those firms individually between now and the end of the year.

Mr. EVERETT. Thank you very much for that detailed analysis, Doctor. The question is, when will you make this available to the public?

Dr. SHOPE. We are working as hard as we can on getting this report out. I think in a matter of a couple of weeks we will have the report to describe to the public the results of these surveys. We have talked about it publicly already in terms of the general trends.

Mr. EVERETT. Would you please give me a date?

Dr. SHOPE. November 15.

Mr. EVERETT. Thank you very much. Ms. Brown.

Ms. BROWN. You probably need to think a little bit about that date, because the Chairman is going to hold you to it.

Mr. HUBBARD. I am sure he will, and we will take that seriously.

Ms. BROWN. Your agency has really come a long way since this subcommittee began examining the readiness of the health care industry for the year 2000. What lessons have you learned and what system improvement have you made as a result of the Y2K readiness efforts?

Dr. SHOPE. I think the biggest lesson we have learned comes from the results of our survey of the 80 firms, the independent audits that were done by the contractor, which were an independent assessment of how is the quality approach to medical device design and manufacturing working in the country. We had a very high level of confidence at FDA about that system.

As you will recall, we were not real enthusiastic about undertaking this effort, thinking that the companies were doing a good job. From the survey results, from the sample that we have looked at, this survey has told us from an independent side that the manufac-

turers do rigorously follow the quality system reg. So I think that gives us some increased degree of confidence on the seriousness with which manufacturers undertake their responsibilities with regard to medical devices.

In terms of other lessons that we have learned, certainly our registration and listing database system which is the system we use to know who is making what, we are in the middle of a re-engineering of that activity. I think we have seen some shortcomings there in terms of the currency and the accuracy of the data. It gets into some of the issues we have had: Is that firm still in business or not? Can we locate them? Those kinds of questions. We are looking at a re-engineering process currently under way now to address some of those issues.

I think those are the two that I take away from this.

Ms. BROWN. Thank you, Mr. Chairman.

Mr. EVERETT. Mr. Udall.

Mr. UDALL. Thank you, and thank you for being here with us today. You express a high degree of confidence in assuring everyone that medical devices will be safe and drug supplies adequate on January 1. GAO is not so confident. They say that your clearinghouse information is insufficient and sometimes inaccurate. With regard to accuracy, I am specifically referring to GAO's analysis of biomedical equipment compliance status information. That differs from what you posted on the Internet. How do you respond to GAO's vote of no confidence in FDA's public information?

Dr. SHOPE. We have looked diligently at any report we have received with any kind of detail or specificity about discrepancies between manufacturers' information and what a health care facility might have uncovered. We have, to date, really found no significant issues in those regards. There have been a few minor differences between performance noted in ways that have really no impact at all on patient health and safety.

I think the database that we have provided to the industry, that is, the health care facilities who have the equipment in front of them and who want a specific answer about a piece of equipment they are very familiar with, the database does provide sufficient information to allow them to do what they need to do to assess their products.

The database was not originally designed to answer general kinds of questions in a way for people who are not familiar with the particular specific medical device. We have heard from health care facilities that the web site is a valuable, useful and helpful activity. We have not heard from any health care facility that there is insufficient data there, that they cannot get what they need from the database or from the manufacturers.

I have only heard of one or two manufacturers that have not been real forthcoming in information about devices. I have to say those manufacturers are well known to us and their products are not the type that are the critical type products, and we are continuing to keep on eye on those couple of manufacturers.

I think I basically disagree with the GAO's conclusions.

Mr. UDALL. Who are those two manufacturers?

Dr. SHOPE. One of the companies is a manufacturer of a nuclear medicine gamma camera type product, and I think the other is a

company that is now out of business actually. There are still some of their products out there.

Mr. UDALL. What are the names of the companies?

Dr. SHOPE. One company is Trionics and the other is Park Medical.

Mr. UDALL. Thank you very much.

I yield back my time, Mr. Chairman.

Mr. EVERETT. Thank you very much.

Let me thank this panel. We have had some very candid conversations over the last couple of years. I appreciate the fact that you recognize that this subcommittee has a great responsibility as well as FDA having a great responsibility. I appreciate the cooperation you have given us. I can assure you that I feel that although we have had some candid conversations, the results have been very beneficial to the American people and particularly our veterans.

I would like to dismiss this panel now with my thanks.

We will have two votes on the floor. That normally means about 20 or 25 minutes. I will recess the hearing until that time.

[Recess.]

Mr. EVERETT. I would like to recognize now the Honorable Hershel Gober, Deputy Secretary of the Department of Veterans Affairs. Mr. Deputy Secretary, if you will please introduce your staff.

STATEMENT OF HON. HERSHEL W. GOBER, DEPUTY SECRETARY OF VETERANS AFFAIRS, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY HAROLD F. GRACEY, JR., PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR INFORMATION TECHNOLOGY; ERNESTO D. CASTOR, VA YEAR 2000 PROGRAM MANAGER; LEONARD R. BOURGET, DIRECTOR, IT POLICY AND PLANNING STAFF, CHIEF INFORMATION OFFICE, VETERANS HEALTH ADMINISTRATION; SALLY L. WALLACE, DIRECTOR, SYSTEMS DEVELOPMENT STAFF AND YEAR 2000 PROGRAM MANAGER, VETERANS BENEFITS ADMINISTRATION; MARK DUROCHER, DIRECTOR, INFORMATION SYSTEMS SERVICE, NATIONAL CEMETERY ADMINISTRATION; AND STEVE WEXLER

Mr. GOBER. Thank you, Mr. Chairman. I have with me Mr. Harold Gracey, who is our acting CIO and who has led the team getting ready for Y2K. I have Ernesto Castro, Sally Wallace, Len Bourget, Mark Durocher, and Steve Wexler. These are the folks that have been working on the Y2K issue.

Mr. EVERETT. If you will, please begin your statement. Please limit the oral statement to 5 minutes, and your entire statement will be made a part of the record.

Mr. GOBER. Thank you, Mr. Chairman. I have a written statement I would like to have submitted for the record.

Mr. EVERETT. Without objection.

Mr. GOBER. I am pleased to appear before this committee. I want to thank you, Mr. Chairman, from our meeting in 1996 when we started the Y2K effort. At that time I pledged to you I would stay engaged on this issue and that I was the person that was responsible for it, and I still maintain that today.

I know that you have other business to do, so with your permission, I am going to make very, very brief remarks so that will leave maximum time for you to ask the questions that you need to ask. I would ask that, as we did in the last hearing, that my associates be permitted to answer those questions that are technical and fall within their realm.

Mr. EVERETT. Without objection.

Mr. GOBER. I am here simply today to reaffirm that benefits payments will be made without interruption and our health care facilities will be operational on January 1 of the year 2000.

I am also aware that Murphy's Law will be in operation, and I have full confidence that the VA team will be ready to work through those unpredictable issues that may arise. We know that veterans and their families are depending upon us, and we shall not fail them.

Mr. Chairman, this concludes my remarks, and we will be happy to respond to your questions.

[The prepared statement of Mr. Gober appears on p. 88.]

Mr. EVERETT. Thank you very much. Let me refer back to our meeting in 1996 when we both realized what an important issue this would be government-wide. I appreciate your commitment to the committee to make sure that the VA was ready and that our veterans would be able to depend on the VA. I congratulate you and your staff for the work that you have done.

You have said in your brief opening statement that the compensation and pension checks would be on time in January. We are very thankful for that. Will they be able to count on their VA medical care?

Mr. GOBER. Yes, sir. We can go into as much detail on the testing that we have done and we will be glad to respond to that. But, yes, I feel confident that we will be able to deliver the health care to the veterans at midnight on December 31. I will not tell you that something will not go wrong, because every day in hospitals we have operational events arise. Even as we are speaking right now something may be going wrong, but we are prepared to take the necessary action to put it back into operation.

I do feel that our veterans will not be threatened, health care will be provided, and the benefits checks will be delivered. Of course, as you know, we are delivering the benefits earlier, as we always do. They will be there on the 30th. We have tested the system through the Treasury and run the programs and they have worked. So I do feel confident.

Mr. EVERETT. How about the department's mission critical systems compliance?

Mr. GOBER. I think I will let Harold answer that.

Mr. GRACEY. As we stated the last time we were here, we have made all our mission critical systems compliant. We have continued to test them. In addition, we put in the moratorium that was mentioned earlier this morning to prevent problems from being introduced into the system during the period from October 15 through March. So we are very confident about the mission critical systems, and have been.

Mr. EVERETT. Mr. Deputy Secretary, what does day one rollover mean to the department? What still needs to be done for VA to be ready for day one?

Mr. GOBER. Ernesto.

Mr. CASTRO. I can answer that. What day one refers to is the preparations for the actual date rollover, which is the last week of December and the first week of January. What we are doing there is making sure we have the process in place and the senior managers available for contact throughout the country. We will be working basically 24 hours, 7 days a week at the hospitals and coordinating the monitoring for the Department and providing this information to the White House Information Coordination Center, which in turn will be notifying the Congress of the status of not just VA, but the rest of the world.

Mr. EVERETT. Mr. Deputy Secretary, do you feel Y2K compliance in the area of VA research is complete or still needs to be done in the research arena?

Mr. BOURGET. If I may, Mr. Chairman. The research program has been dealt with in two ways, programmatically from headquarters and the second through the medical center management chain. Each medical center director has been assigned responsibility for ensuring that the research program has done its compliance work and is now doing contingency planning work. We have certifications from the medical center directors and the VISN directors that that research activity has been carried out.

There are details still to be done. As GAO pointed out this morning, we are not through. We are still working the issue. So there are things that remain, but I am confident that the medical center management will see those through to completion.

Mr. EVERETT. How many hospitals have biomedical devices on loan from the hospital to the patients at home, and how many of these devices have been certified Y2K compliant?

Mr. BOURGET. The home health care programs and the prosthetics programs at the VA medical centers have examined the devices that we have placed in patient homes. They have developed check lists to go over the care of the patient in the home. They have assessed the threat to the patient in their home situation. They have done that with their current census, and they will revisit that closer to the rollover to ensure that patients in their home are not in danger, for example, from failure of electrical power.

We have not found any risk in terms of the equipment that is placed in the home. The greater threat may be the environment of care that the patient will be in, in which case there are plans at the medical centers individually to bring patients back into the hospitals for the rollover where they will be guaranteed sustained electrical power.

Mr. EVERETT. Mr. Deputy Secretary, the IG has expressed concern that VHA has not routinely received certification of the continued use of non-compliant biomedical devices beyond December 31, 1999. How many hospitals have emergency lighting and alternative cooking heat in the kitchen? During an emergency how can the hospital cook in the dark?

Mr. BOURGET. Each hospital has done a test of their emergency electrical generator, and where there were deficiencies, for exam-

ple, a kitchen in the dark, those deficiencies should have been remedied by now. I will certainly go back and check on that in particular, Mr. Chairman.

There were deficiencies when they ran the test. There were problems. For example, one hospital found all of its elevators were on emergency power but none of the elevators had lights. The cabin lights were on a different circuit. They have now fixed that problem.

Another hospital found that its command center, which would be operational over the rollover, was not under emergency power. That has been remedied.

There have been many learning opportunities from the emergency electric generator test, and those deficiencies that were found are being corrected.

Mr. EVERETT. I am told by staff that some hospitals tested their generators for about 8 hours; others as little as 30 minutes.

Mr. BOURGET. The recommendation, sir, was that they all test for 8 hours.

Mr. EVERETT. Have they all tested for 8 hours?

Mr. BOURGET. No, sir. Some did conduct shorter tests.

Mr. EVERETT. Thirty minutes or less?

Mr. BOURGET. That I have not heard. That is news to me, sir. I will certainly pursue that with your staff.

Mr. EVERETT. Ms. Brown.

Ms. BROWN. In August of 1999, after concurring with the auditor's findings and providing appropriate actions to implement the recommendations, Mr. Gracey, the Acting Assistant Secretary for Information Technology, requested additional IG assistance to help assess his Y2K implementation efforts. I like that kind of attitude, Mr. Gracey.

Mr. GRACEY. Thank you.

Ms. BROWN. How will VA handle the rollover from a staffing perspective? Can you give us more details?

Mr. GRACEY. Yes, ma'am, I would be glad to. We have a plan to activate several sites around the country specifically for the weekend period, Friday night, the 31st, and the morning of the 1st, although there will be staff there longer.

Myself and a number of other senior staff will be at Martinsburg, WV, which is our normal emergency management center, where we will be collocated with the Veterans Health Administration's management. Veterans Benefits Administration will be at an emergency center at 1800 G Street. Ernesto is going to be in the White House Information Coordination Center, which is also located at 1800 G Street contiguous to our space. National Cemetery Administration will do the same. Public Affairs will do the same.

We have made arrangements to be in contact with each other and also with everyone else who is a significant organization by a variety of means of communication. We think we are set up in a mode where we will be able to react to whatever happens during that period.

Ms. BROWN. Thank you. I have one other thing, Mr. Gracey. In a letter I submitted for the record during my opening statement the VA Inspector General was very complimentary of your efforts to bring the department into Y2K compliance. He, however, identi-

fied six areas of concern. I want to go through a few of them in the time that we have, and then I would like to submit the others for follow-up questions.

Some VA locations have some contingency plans that were not customized to address individual facility plans. How has this been addressed?

Mr. GRACEY. We followed up. That was the Veterans Health Administration side where they appeared to have done a skimpy job or resubmitted the template. Those plans have been redone, and to the best of my knowledge they are all now complete as of the latest version.

Mr. BOURGET. Yes, that is correct. Further, we developed a check list for reviewing contingency planning. We made site visits to 13 medical centers and reviewed their planning process and their plans, and then we gave those check lists to the VISN directors and encouraged them to go out to the hospitals that we were unable to visit and to do an on-site review of contingency planning at each medical center.

Ms. BROWN. IG has been advised that some of the buildings leased by VA from General Services Administration are still not Y2K compliant. What is VA's risk and what is being done to protect the department and its customers in these buildings?

Mr. GRACEY. We are down now to only one GSA leased building that has not been certified compliant. That happens to be the VA regional office in Washington, DC. We are expecting advice from GSA later this week on exactly what the status of that building is, and we expect to have that resolved sometime in the next 63 days. All the rest, including the out-based sites, are associated with buildings that have been certified compliant or that we have made compliant. So we are very comfortable with that.

Ms. BROWN. I really want to thank you all for being the leader in this area. Not just showing that VA can do a good job, but being the leader as far as other agencies are concerned. This will be extremely important to the veterans and their families with the uncertainties in the country. So thank you again.

Mr. Chairman, I yield back my time.

Mr. EVERETT. I thank the gentlelady.

I have a couple of other questions. Why haven't all the hospitals in the field used the Y2K VISTA data management software for biomedical devices provided by VACO? VISN 5 made good use of it and has provided the subcommittee with a detailed list of the Martinsburg VAMC biomedical equipment inventory. My understanding is very few have done that.

Mr. BOURGET. Mr. Chairman, that was a tool that we developed during the past 2 years to assist the hospitals based on an inventory system that they are using. The specific Y2K tool that we developed enabled them to process Y2K compliance issues with the medical devices. Mr. Steve Wexler, our chief biomedical engineer, can perhaps address why not all facilities may have availed themselves of that tool.

Mr. WEXLER. What you are looking at is an existing system that has been put in place in all VHA hospitals to track critical medical equipment from basically its infancy through when it is turned in.

All medical centers, as you may know, are periodically reviewed by the Joint Commission on Accreditation for Healthcare Organizations. One of the things the JCAHO inspectors look for is an inventory listing of medical devices that are tracked for critical maintenance activities and for hazards and recalls.

Actually it has been in place since 1985. For all our facilities that have been reviewed by the Joint Commission on Accreditation for Healthcare it has never been pointed out as a deficiency to us.

Mr. EVERETT. How many actually use the system?

Mr. WEXLER. To my knowledge, they all do.

Mr. EVERETT. I will have to tell you that that is not the subcommittee's information. I would like clarification on that.

In addition to being ready for Y2K, have there been other lessons learned to improve preparedness and experience gained in the areas of VA's disaster and emergency relief missions? We have gone through extensive work here, and I am sure there have been some side benefits.

Mr. GOBER. I think it has been very useful, Mr. Chairman. All the hospitals now have a contingency plan. It has helped us in our other contingency planning for natural disasters and other emergency events. So I think it has been a good event.

I want to thank you also for your efforts and Ms. Brown's efforts and the members of your staff for helping us. They have been very helpful to us when they go visit. We cannot visit all the hospitals, but when the staff goes out and visits, they do bring these situations to our attention and we immediately take corrective action.

As we were talking earlier, I think we have picked all the low hanging fruit now, and we are going to continue to reach for the higher fruit to not see this as a negative aspect. I think Y2K has been a very, very positive experience for us. That's why I can sit here and say that I feel reasonably confident that we are going to be okay.

So I think, yes, it has been a very positive experience and it has helped the VA.

Mr. EVERETT. I want to thank the panel and you, Mr. Deputy Secretary. At this point I would like to yield to Ms. Brown for her closing statements, and then I will have a closing statement.

Ms. BROWN. Thank you, Mr. Chairman. I am proud of the work that this subcommittee has done over the past 2 years. In large part because of your efforts and some heavy lifting by the General Accounting Office, VA is now considered a leader in the Y2K preparation. But more importantly, through your leadership, America's veterans and their families have had the VA benefits and services, upon which they depend, inoculated against the worst effects of the feared Y2K bug. Now, even if VA's computers become infected through their interaction with "other children in the neighbor," I think the department would get but a mild case of the "glitches."

I am confident, also, that the prognosis would be good for a quick and full recovery.

Thank you.

Mr. EVERETT. I thank the gentlelady. It is apparent to this subcommittee that the VA has made a tremendous effort over the past 3 years addressing and correcting Y2K problems that could have

severely disrupted critical benefit delivery and health care services to America's veterans.

Mr. Gober, I applaud you as Deputy Secretary of Veterans Affairs and the VA's chief operating officer for leading the charge, mobilizing the troops, and averting what had the potential to be a great disaster. I think veterans can breathe a lot easier about receiving their benefits on time and getting safe health care and using life saving medical devices that will not fail them, as well as not being deprived of prescriptions and medical supplies that they need in their daily lives.

I will have to say that considering the complexity of the VA—and we all know it is a very complex system—in my opinion the VA is above all other government agencies in reaching Y2K compliance.

This has been one of the most difficult management challenges to face government since World War II. You all and all the VA employees, including the Office of the Inspector General, have met the challenge most impressively. The success of this effort is proof positive that when this department puts its will to solving a difficult problem, it can do the job.

I look forward to seeing this kind of success replicated in other challenges the VA faces. I know you do not intend to rest on these accomplishments, because the VA must continue its diligence in testing and refining business and contingency plans and day one plans.

I have no doubt that somewhere, somehow, despite all the best efforts, some, hopefully minor, Y2K problems will likely occur on January 1, 2000, and the VA must be fully prepared to deal with them effectively. That means being fully prepared for the worst case scenario.

I would like to thank the GAO again for its tremendous effort and contributions in analyzing both the potential problems facing the VA and the FDA and the effectiveness of these efforts to overcome them. GAO has performed a highly significant public service for the VA, FDA, veterans, and all Americans.

I also want to acknowledge the efforts of the FDA. Since our last hearing in April, FDA has addressed many of the concerns that were raised in that hearing. I urge FDA to continue moving forward aggressively to complete its evaluation of Y2K compliance in the pharmaceutical and biomedical devices industry. The American public needs to be informed and has every right to know if any medical products could put them at risk, and if the public is to be confident about the supply of vital medications, it must be confident of the information available to them.

I truly hope the new year will prove to be uneventful for our veterans in terms of computers. It is simply amazing how reliant we have become on those darn machines in the last few years.

I would also like to congratulate my Ranking Member for her interest in this and sticking with us and asking the tough questions when they needed to be asked.

This hearing is adjourned.

[Whereupon at 11:38 a.m. the hearing was adjourned.]

APPENDIX

RANKING MEMBER CORRINE BROWN
Opening Statement
Oversight and Investigations Subcommittee Hearing
Year 2000 Readiness in the VA

October 28, 1999

Well, here we are again, Mr. Chairman, trying to reassure America's veterans and their families that VA hospitals will operate normally on New Year's morning, and that all checks will be delivered on time.

Today it will be nice to hear VA report on how it is ready to roll over into the Year 2000, and how it received two "A's" last month from a House oversight committee that was grading Y2K efforts government-wide.

It also will be nice to hear the Food and Drug Administration say how much confidence it has that essential medical supplies will be available, that medical devices will function as intended, and that there will be a safe and adequate supply of drugs available.

I am concerned, however, Mr. Chairman, that all of today's nice talk will be meaningless if VA has to walk its walk in a community shut down by a massive power outage or in a town where the water supply has been cut off for a long period of time.

Disruptions on a large scale would, of course, be beyond VA's control. I am sure that VA will answer today's pop quiz questions on this concern by saying that each of its facilities is individually planning for such contingencies. The real test, Mr. Chairman, on how well VA's decentralized health care system has done its local planning will not be given this morning. That test will start at 12:01 a.m. on Saturday, January 1, and continue through the 29th of February.

I appreciate the hard work and long hours that so many VA employees have already given in preparation for the Department's roll over to Year 2000. I especially appreciate the dedication of those who plan to give up their New Year's holiday to ensure that America's hospitalized veterans might celebrate the new millennium in comfort and safety. To the Department of Veterans Affairs and all those it serves, I wish you a smooth conversion and an uneventful New Year.

Mr. Chairman, I know that the General Accounting Office has some continuing concerns. As we hold this fifth in a series of Y2K hearings, I appreciate the diligence of the GAO audit staff in keeping VA's and the FDA's feet to the fire over the past two years.

VA's Inspector General also has been active in assisting the Department's Y2K implementation efforts from the beginning. Inspector General Richard Griffin is not testifying today, Mr. Chairman, but I would ask that his letter to me dated October 25, 1999, outlining the work of his office in this matter, be made a part of the record.

A June 1999 Office of Inspector General audit found that VA's Y2K efforts were well organized and focused on those mission critical systems that must be compliant to ensure that veterans receive uninterrupted services. VA reported to the Inspector General that it has successfully completed implementation of all mission critical systems and is now engaged in completion of necessary contingency planning actions.

The Inspector General's June audit identified areas where VA's Y2K implementation efforts could be strengthened. VA concurred with both the audit findings and recommendations, and has provided appropriate implementation actions. In August 1999, the Acting Assistant Secretary for Information and Technology requested additional IG assistance to further assess Y2K implementation efforts. I like that kind of attitude.

Mr. Chairman, I am proud of the work that this Subcommittee has done over the past two years in first sounding the clarion call to readiness and then sticking doggedly to the daunting challenge of making the Federal government's second largest agency Y2K compliant.

Mr. Chairman, in large part because of your efforts -- and some heavy lifting by the General Accounting Office -- VA now is considered a leader in Y2K Federal preparedness. But more importantly, through your leadership, America's veterans and their families have had the VA benefits and services, upon which they depend, inoculated against the worst effects of the feared Y2K bug. Now, even if VA's computers become infected through their interaction with the "other children in the neighborhood", I think the Department would get but a mild case of the "glitches". I am confident, also, that the prognosis would be good for a quick and full recovery.

Statement of Joel C. Willemssen, Director, Civil Agencies Information Systems, Accounting and Information Management Division, United States General Accounting Office

Mr. Chairman and Members of the Subcommittee:

Thank you for inviting us to participate in today's hearing on the Department of Veterans Affairs' (VA) efforts to address the Year 2000 (Y2K) computer problem.[1] My testimony today will focus on the Y2K readiness of automated systems that support the delivery of veterans' benefits and health care services, the compliance status of biomedical equipment used in patient care, and the Y2K readiness of the pharmaceutical and medical-surgical manufacturers on which VA relies. I will also share with you information on the Food and Drug Administration's (FDA) Y2K efforts to address biomedical equipment and pharmaceutical products.[2]

In brief, VA continues to make progress in addressing the Y2K problem. It has established a moratorium on software changes and has developed a Day One plan to minimize risks associated with the rollover period. However, some critical tasks remain to be completed. For example, only about 10 percent of the Veterans Benefits Administration's (VBA) 58 regional offices have tested their business continuity and contingency plans. And, inaccuracies in monthly reports submitted by the Veterans Health Administration's (VHA) medical facilities make it difficult to determine their progress in renovating facility systems, telecommunications systems, commercial-off-the-shelf (COTS) software, computer platforms, and medical devices. Further, VHA has

[1] As is widely known by now, for the past several decades computer systems have often used two digits to represent the year, such as "98" for 1998, in order to conserve electronic data storage and reduce operating costs. In this format, however, 2000 is indistinguishable from 1900 because both are represented as "00." As a result, if not modified, systems or applications that use dates or perform date- or time-sensitive calculations may generate incorrect results beyond 1999.

[2] Biomedical equipment refers to both medical devices regulated by FDA, within the Department of Health and Human Services, and scientific and research instruments, which are not subject to FDA regulation. Pharmaceutical products also fall under FDA's regulatory authority.

not implemented our prior recommendation to review the test results for biomedical equipment used in critical care/life support environments. It is crucial that VA address these issues if the department is to continue to reliably deliver benefits and other health care services through the turn of the century.

FDA, for its part, has made progress in making compliance information on biomedical equipment available to users through its Federal Y2K Biomedical Equipment Clearinghouse. It is also conducting surveys to determine the Y2K readiness of pharmaceutical, biological, and consumable medical[3] products manufacturers. FDA has also recently addressed our concern about the lack of independent verification and validation of critical care/life support biomedical equipment certified compliant by manufacturers. Specifically, it has reviewed a sample of these manufacturers' Y2K activities, including risk management, test planning and procedures, implementation, and contingency planning. In the limited time remaining, FDA still needs to issue its final report to the Department of Health and Human Services (HHS) summarizing the results of its review of manufacturers' Y2K activities and make these results available to the public.

VA IS MAKING PROGRESS ON SYSTEMS BUT CRITICAL TASKS REMAIN

Like many organizations, VA faces the possibility of computer systems failures at the turn of the century due to incorrect information processing relating to dates. This could

[3] Consumable medical products are expendable, disposable, or non-durable supplies used for the treatment or diagnosis of a patient's specific illness, injury, or condition. Examples include surgical gloves and intravenous tubing.

make veterans who are eligible for benefits and medical care appear ineligible. If this happens, the issuance of benefits and the provision of medical care that veterans rely on could be delayed or interrupted.

At your request, Mr. Chairman, we have been monitoring and evaluating VA's actions to address the Y2K problem since 1996.[4] We have also made many recommendations to reduce the risk associated with Y2K failures, and VA has been responsive to these recommendations. For example, VBA changed its strategy from relying on new Y2K-compliant systems to fixing the current systems in order to address the risk that the new systems would not be completed in time. In 1998, VBA also reassessed its mission-critical efforts for the compensation and pension on-line application and the Beneficiary Identification and Record Locator Sub-System, as well as other technology initiatives to help ensure that these critical undertakings were completed in time. Simultaneously, VHA issued its Patient-Focused Year 2000 Contingency Planning Guidebook to its medical facilities, describing actions they could take to minimize Y2K-related disruptions to patient care. More recently, both VBA and VHA developed business continuity and contingency plans that address mission-critical systems, core business processes, regional offices, and medical facilities.

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[4] See *Year 2000 Computing Crisis: Actions Needed to Ensure Continued Delivery of Veterans Benefits and Health Care Services* (GAO/AIMD-99-190R, June 11, 1999), *Year 2000 Computing Crisis: Action Needed to Ensure Continued Delivery of Veterans Benefits and Health Care Services* (GAO/T-AIMD-99-136, April 15, 1999), *Year 2000 Computing Crisis: Compliance Status of Many Biomedical Equipment Items Still Unknown* (GAO/AIMD-98-240, September 18, 1998), *Year 2000 Computing Crisis: Progress Made in Compliance of VA Systems, But Concerns Remain* (GAO/AIMD-98-237, August 21, 1998), *Veterans Affairs Computer Systems: Action Underway Yet Much Work Remains to Resolve Year 2000 Crisis* (GAO/T-AIMD-97-174, September 25, 1997), *Veterans Benefits Computer Systems: Risks of VBA's Year-2000 Efforts* (GAO/AIMD-97-79, May 30, 1997), and *Veterans Benefits Modernization: Management and Technical Weaknesses Must Be Overcome If Modernization Is To Succeed* (GAO/T-AIMD-96-103).

In addition, VA has reported to the Office of Management and Budget (OMB) that it completed renovating and implementing the mission-critical applications supporting its 11 systems areas as of March 31, 1999. As shown in table 1, VBA has six of these areas, and VHA has two.

Table 1: Reported Status of VA's Mission-Critical Computer Systems Areas and Their Applications

Component/Office (Number of systems)	Systems Area	Number of Applications Renovated or Replaced
Veterans Benefits Administration (6)	Compensation and Pension	30
	Education	24
	Insurance	3
	Loan Guaranty	19
	Vocational Rehabilitation	4
	Administrative	27
	Total	**107**
Veterans Health Administration (2)	Veterans Health Information Systems and Technology Architecture	105
	Veterans Health Administration Corporate Systems	95
	Total	**200**
National Cemetery Administration (1)	Burial Operations Support System/Automated Monument Application System	1
	Reengineer	1
	Total	**2**
Office of Financial Management (2)	Personnel and Accounting Integrated Data	8
	Financial Management System	1
	Total	**9**
VA Total		**318**[a]

Source: VA. We have not independently verified this information.
[a]Of this total, 316 applications were renovated and two were replaced.

Although VA has made progress, when we testified[5] this past April, the department still had numerous Y2K issues to address. Specifically, (1) VBA and VHA had not completed testing of their mission-critical systems to ensure that they could reliably accept future dates, (2) VHA had not completed assessments of its facility systems,[6] (3) VHA's pharmaceutical operations were at risk because the automated systems supporting its consolidated mail outpatient pharmacies (CMOP) were not Y2K compliant, (4) VHA had not defined the CMOP systems as mission-critical in its quarterly report to OMB, and (5) VHA did not know whether its medical facilities would have a sufficient supply of pharmaceutical and medical/surgical supplies on hand because it did not have complete information on the Y2K readiness of these manufacturers. To address these issues, we made the following recommendations to the Secretary of Veterans Affairs:[7]

- complete Y2K testing of VBA and VHA mission-critical systems—including systems acceptance testing,[8] full forward-date testing,[9] end-to-end testing, and business process simulation testing on compliant platforms;
- set deadlines to complete assessment, renovation, validation, and implementation of VHA's facility systems;
- develop business continuity and contingency plans for VHA CMOPs to ensure an uninterrupted supply of medications to veterans in the event of Y2K problems at these facilities;

[5] GAO/T-AIMD-99-136, April 15, 1999.
[6] Facility systems include building-related equipment such as elevators, heating, ventilating, and air conditioning equipment, lighting systems, security systems, and disaster recovery systems.
[7] GAO/AIMD-99-190R, June 11, 1999.
[8] Systems acceptance testing verifies that the complete system—the full component of applications software running on the target hardware and system software—satisfies specific requirements and is acceptable to users.
[9] Forward-date testing verifies that the system is able to process using future dates in 2000 and beyond.

- reassess VA's decision not to report CMOP systems as mission-critical; and
- seek the assistance of FDA and industry trade associations in obtaining information on the Y2K readiness of specific pharmaceutical and medical/surgical suppliers[10] that did not respond to VHA's survey, and publicize the results in a single data clearinghouse.

VA Has Been Responsive to Recommendations

VA generally agreed with our recommendations, and actions to implement them have either been taken or are underway.

- Both VBA and VHA have completed systems acceptance and forward-date testing. VBA completed systems acceptance testing of its benefits delivery applications and also tested its payment systems' ability to process benefits in January 2000, in conjunction with the Department of the Treasury's Financial Management Service and the Federal Reserve System. This testing was completed in July 1999. Likewise, VHA completed Y2K systems acceptance testing of its mission-critical hospital systems. In addition, in August 1999, VHA's independent verification and validation test group forward-date tested 56 hospital applications.[11]
- VHA issued a policy directive on July 30, 1999, stating that its medical facilities had to make a decision on renovation strategies by September 1, 1999, for those facility systems components and interfaces whose Y2K status was noncompliant, conditionally compliant, or unknown. The directive also required these facilities to

[10] These include manufacturers and distributors.
[11] These 56 applications, which run at most VA health facilities, were chosen for their date intensiveness and business criticality. Included among the applications tested were inpatient and outpatient pharmacy, radiology, laboratory, and surgery.

establish specific contingency plans for each of these systems. According to the Y2K project office, all of the medical facilities have met this requirement.

- VHA's CMOPs have developed business continuity and contingency plans that address important issues such as the loss of electrical power, telecommunications with the medical centers, and their automated dispensing machines. These plans should reduce the risk that Y2K disruptions will impair the CMOPs' ability to continue filling and delivering veterans' prescriptions.
- In its August 1999 report to OMB, VA said that renovation of the vendor-supplied CMOP dispensing systems were on schedule to make all seven CMOPs Y2K compliant by September 30, 1999.
- VA has worked with FDA and various other industry associations to obtain and share Y2K-readiness information on the Y2K compliance status of pharmaceutical and medical-surgical manufacturers. It has posted results on its Internet home page (www.va.gov).

VA Established a Moratorium on Software Changes

To minimize possible disruptions to agencies' Y2K readiness resulting from system changes, OMB, in a May 14, 1999, memorandum to heads of departments and agencies, requested that agencies establish a process to ensure that the effect on Y2K readiness is considered prior to establishing new requirements or changes to information technology

systems.[12] We had previously testified that agencies should institute such a process to ensure that software changes do not negatively affect Y2K readiness.[13]

In response to OMB's memorandum, VA issued a October 14, 1999, memorandum to department heads imposing a moratorium on implementing new systems, changes to existing systems, or third-party upgrades to VA's information technology systems between October 15, 1999, and March 31, 2000. The intent of the memorandum was to ensure that the department incorporates Y2K change management procedures. It further stated that in those instances in which software changes were necessary—such as when compliant software had to be modified due to legislative or other agency requirements—it would be necessary to test all changes and recertify the software's compliance.[14]

VA has also defined a process for requesting waivers for software changes or upgrades during this time. Specifically, waivers must be justified by the VA administration requesting them and concurred with by that administration's chief information officer (CIO), architecture review board, or senior information technology official. The request is then submitted to VA's Principal Deputy Assistant Secretary for Information and Technology for approval.

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[12] *OMB Memorandum M-99-17: Minimizing Regulatory and Information Technology Requirements that Could Affect Progress Fixing the Year 2000 Problem, May 14, 1999.*

[13] *Year 2000 Computing Crisis: Readiness Improving, But Much Work Remains to Avoid Major Disruptions* (GAO/T-AIMD-99-50, January 20, 1999).

[14] Examples of software that will be modified include applications affected by cost-of-living adjustments that usually take effect in January.

Prior to the department's issuing this moratorium, VBA had developed and issued a similar moratorium to all VBA offices on July 29, 1999. This memorandum imposed a moratorium on the deployment of new application changes or third party product upgrades between September 1, 1999, and April 1, 2000, and stated that exceptions to the moratorium included emergency fixes and legislatively mandated changes such as cost-of-living adjustments.

VHA has not yet issued specific instructions on how it will implement the department's moratorium. However, according to VHA's Y2K project office, it plans to issue guidance to its offices and medical centers based on VA's memorandum. According to VHA's Y2K project manager, this guidance was not developed earlier because VHA was waiting for the department to issue its memorandum.

VA Has Developed a Day One Strategy

As we note in our business continuity and contingency planning guide,[15] developing a Day One risk reduction strategy and procedures for the period between late December 1999 and early January 2000 is a key element in contingency planning. Earlier this month, we issued a more specific guide on Day One planning.[16] In addition, OMB, on October 13, 1999, issued a memorandum to the heads of selected departments and

[15] *Year 2000 Computing Crisis: Business Continuity and Contingency Planning* (GAO/AIMD-10.1.19, August 1998).
[16] *Y2K Computing Challenge: Day One Planning and Operations Guide* (GAO/AIMD-10.1.22, October 1999).

agencies[17] instructing them to develop Day One plans and encouraging them to use our guide in the development of these plans. OMB required that the plans address seven areas: (1) schedule of activity, (2) personnel on call or duty, (3) contractor availability, (4) workforce communication, (5) facilities and services to support workforce, (6) security, and (7) public communications.

VA and its agencies have developed a high-level Day One strategy that should help the department manage risks associated with the January 1 rollover and better position it to address any potential disruptions. This strategy addresses each of the seven areas required by OMB:

- a time line of events between December 31 and January 1;
- a personnel strategy and leave policy that identifies key managerial and technical personnel available to support Day One operations;
- a statement that its administrations reviewed vendor service agreements and revised them to ensure that contractor support and other needs for the rollover period are met;
- a communications structure for workforce reporting during the rollover period. Under this structure, VBA regional offices plan to report to regional representatives, who plan to report to a national VBA information coordination center, located at VBA headquarters in Washington, D.C; VHA medical centers plan to report to their Veterans Information Service Network (VISN)[18] representative, who plans to report to a national VHA information coordination center located in Martinsburg, West

[17] *OMB Memorandum M-00-01: Day One Planning and Request for Updated Business Continuity and Contingency Plans, October 13, 1999.*
[18] Veterans Integrated Service Networks are 22 regional organizations encompassing medical centers, nursing homes, and domiciliaries.

Virginia. The VBA and VHA national information coordination centers plan to report to the VA national information coordination center, also located in Martinsburg;

- a statement that its facilities have addressed facility and support services for its workforce in their business continuity and contingency plans. In addition, the Day One plan requires regular "health" checks to ensure that these services remain available during the rollover period;
- a statement that the VA computer systems and data centers are being secured and additional security has been extended to the networks to increase protection during the rollover period; and
- a VA Office of Public Affairs information communications center to support the VA national information coordination center and direct public communications through the Joint Public Information Center that the President's Council on Year 2000 Conversion Council plans to set up for the rollover period.

VA's Day One plan also describes preparation activities that VA has completed or plans to complete in order to help minimize potential Year 2000 disruptions to benefits delivery and health care. For example, VBA plans to process most of its regular, recurring benefits payments so that they will be available to veterans on December 30, 1999. This, according to the plan, will greatly mitigate possible Y2K interruptions of benefits payments.

VA Has Developed Business Continuity and Contingency Plans

According to VA's August 1999 report to OMB, its regional offices and medical facilities have completed business continuity and contingency plans. In addition, according to VA, a selected number of these plans have been reviewed by their respective Y2K project offices. Specifically, VBA's Y2K project office reviewed the plans of its regional offices and found that they met VBA requirements. We reviewed 15 of the 58 VBA regional plans and found that they address resources, staff roles, procedures, and timetables for implementation, as well as risks and risk mitigation.

In reviewing the 58 medical facilities' business continuity and contingency plans, VHA's Y2K project office concluded that while overall the plans adequately addressed contingency planning, the plans of 14 facilities were deficient. These deficiencies included the lack of a schedule of critical events; lack of a policy statement describing the authority, responsibility, and procedures for Y2K contingency planning; and missing contingencies for specific functional areas, such as intensive care or operating rooms. The project office asked the 14 facilities to address these deficiencies and submit revised plans, which it is currently reviewing.

We reviewed the plans of 29 medical facilities to determine their completeness,[19] and found that, in some cases, the schedule of critical events and execution timelines were not specific to the medical facility. Additional specificity, such as time lines relevant to the

[19] The plans chosen for review included 19 medical facilities in the three VISNs that we have been monitoring, and four facilities that are co-located with a CMOP.

medical facility and specific dates for accomplishing tasks contained in the time lines, would help make it easier for facility staff to implement the plan, and help minimize confusion that might result if plans needed to be activated. A second issue concerned the lack of medical facility coordination with VHA's seven CMOPs. This is especially important since the seven CMOPs supply about 50 percent of VA's prescriptions to veterans. VHA's guidance, however, only required sites that were co-located with a CMOP to coordinate their plans with that CMOP alone.

We discussed these issues with representatives of VHA's Y2K project office. They agreed with our concern regarding the time lines and said that the sites had been advised to ensure that these were sufficiently specific. In addition, the VHA Y2K project manager told us that all CMOPs had been advised to discuss their business continuity and contingency plans with the medical facilities that they support so that they are aware of them.

VA Has Not Completed Testing of Its Business Continuity and Contingency Plans

Testing of business continuity and contingency plans is key to determining whether the contingencies are capable of providing the needed level of support to core business functions and whether they can be implemented in a reasonable amount of time. In

addition, testing can show where plans need to be updated or changed. We previously testified that testing of plans should be completed by September 30, 1999.[20]

As of October 22, 1999, only five of VBA's 58 regional offices had completed testing of their business continuity and contingency plans. VBA initially asked that each regional office complete a "desktop" exercise[21] of its plan by September 30, 1999, during which the business continuity and contingency plan team and other critical staff would simulate an emergency situation. According to VBA's Y2K project manager, the project office is now requiring the regional offices to complete this exercise by November 15, 1999. It is critical that VBA regional offices test their plans to ensure that their contingencies are sufficient to maintain an acceptable level of service and that the contingencies can be implemented in a feasible time frame.

All of VHA's medical facilities reportedly have completed emergency drills. These drills, conducted under controlled conditions to ensure no impact on patient safety, required each facility to turn off its local electric supply and rely on backup generators. The medical facilities identified deficiencies in their plans as a result of these drills. For example, one site found that its generator was not capable of powering the entire hospital.

[20] GAO/T-AIMD-99-50, January 20, 1999.
[21] VBA's "desktop" simulation was not to include the actual establishment of an emergency operations center or emergency backup sites.

It has now contracted for an additional backup generator to ensure that all critical areas can be powered. Other sites found that some of their mission-critical areas were not linked to the backup generator, and have since contracted for additional work to link them.

While VHA's medical centers have tested their facilities' ability to handle power outages, other portions of their business continuity and contingency plans, such as dealing with potential water and gas shortages, have not been tested. Losses in these areas can have an impact on patient care. Specifically, a VHA medical facility recently suffered a loss of water, resulting in a loss of the steam plant, cooling towers, and fire suppression system. This facility suggested that other facilities reevaluate their contingencies in view of these losses.

Monthly Reports Do Not Accurately Reflect
Y2K Status of Noncompliant Systems

All of VHA's VISNs/medical facilities are required to prepare monthly reports on their Y2K progress in assessing, renovating, validating, and implementing compliant systems. Specifically, they report on their Y2K status in six areas: locally developed software, COTS software, computer platforms, telecommunications systems, facility systems, and medical devices. These reports are used by VHA to monitor progress in addressing Y2K issues and to identify problem areas.

VHA's summary report for August 1999 indicated that the medical centers had made limited progress in renovating their remaining noncompliant facility systems and telecommunications systems. Specifically, it showed that overall, only 43 percent of the facility systems and 41 percent of the telecommunications systems at the medical facilities had completed renovation. The numbers were somewhat higher for COTS software, at 55 percent, and computer platforms, at 65 percent. The highest renovation number was for locally developed software products, at 94 percent. We discussed these renovation statistics with VHA's Y2K project manager, who told us that the summary report may not be accurate because facilities are not clear on whether to report on systems or on the components that make up the systems.

During visits to selected medical facilities we confirmed that their individual and summary reports did contain errors. For example, some of the VISN percentages in the August report exceeded 100. The Y2K office has also contacted selected medical facilities and acknowledged that the reports have errors. To address this issue, the Y2K office is currently contacting and visiting sites to discuss these reporting issues. It is critical that the medical facilities accurately report their Y2K progress in renovating their noncompliant systems so that top management within VA can identify problem areas and take prompt and appropriate action.

VHA HAS MADE PROGRESS IN DETERMINING Y2K COMPLIANCE STATUS OF BIOMEDICAL EQUIPMENT

The question of whether VHA's medical devices such as magnetic resonance imaging (MRI) systems, x-ray machines, pacemakers, and cardiac monitoring equipment can be counted on to work reliably on and after January 1, 2000, is critical to VHA. To the extent that biomedical equipment uses computer chips, it is vulnerable to the Y2K problem. In the medical arena, such vulnerability carries with it possible safety risks.

VA Continues to Collect Compliance Information on Biomedical Equipment

In April, we testified before this Subcommittee that VHA was continuing to collect information from biomedical equipment manufacturers on the Y2K compliance status of equipment in its inventory.[22] As shown in table 2, a little over half of the manufacturers in VA's database reported directly to the department that their products are compliant as of October 25, 1999. Since we last testified, VA has created a new compliance category to capture the increasing number of manufacturers that have web sites with Y2K information. VA reported that about 24 percent of the manufacturers in its database (1,393) are in this new category.

[22] GAO/T-AIMD-99-136, April 15, 1999.

Table 2: Status of Manufacturer Responses to VHA as of October 25, 1999

Manufacturer response	Number of Manufacturers	Percentage of manufacturers
Manufacturers with web site information	340	24
Compliant manufacturers[a]	720	52
Noncompliant manufacturers[b]	33	2
Conditional-compliant manufacturers[c]	40	3
Pending manufacturers[d]	11	1
Manufacturers merged or bought out	241	17
Nonresponsive manufacturers[e]	8	1
TOTAL	1,393	100

[a]For inclusion in this category, 100 percent of a manufacturer's products had to be considered compliant.
[b]For inclusion in this category, only one of a manufacturer's products had to be considered noncompliant.
[c]For inclusion in this category, the manufacturer had to have no noncompliant devices, no pending devices, and at least one conditional-compliant device.
[d]For inclusion in this category, the manufacturer had to have no noncompliant devices and at least one device that is pending.
[e]For inclusion in this category, VHA had to have not received compliance information from the manufacturer.

Source: Veterans Health Administration. We did not independently verify these data.

For nonresponsive manufacturers, VHA's Y2K project manager told us that the project office had contacted the facilities that reported devices in their inventories from these manufacturers and instructed them to make a decision on their disposition. The project manager further stated that none of these devices was used in critical care or life support

functions, and that the facilities with this equipment had been instructed to plan for contingencies in the event any of them experience a Y2K-related failure.

In April 1999, VHA issued a policy establishing (1) a review process for medical devices whose compliance status was unknown, noncompliant, or conditionally compliant, and (2) options for what action should be taken on these devices. Options included replacing or retiring the equipment, or using it as-is.[23] Medical facilities were to complete these reviews by June 1, 1999, for equipment whose Y2K compliance status was either unknown or noncompliant, and September 1 for equipment whose status was conditionally compliant. In each case, the medical facility director's approval of the disposition decision was required. For noncompliant equipment, the medical center was required to assess the level of risk if it continued to use the equipment, and determine what risk such use posed to patient health and safety. To make this assessment, medical facilities were to consider such questions as whether the device is used for critical care, or if the device used date-sensitive data, such as sequencing patient data results.

To track the compliance status of its biomedical equipment, VHA uses a monthly status report on medical devices based on information provided by the VISNs/medical facilities.

[23] Conditionally compliant equipment requires user intervention to function in all aspects upon the year 2000 change. These changes include manufacturer software or hardware updates, or a one-time user action, such as turning the equipment on/off. Noncompliant equipment means a medical device will not function properly in all aspects upon the year 2000 change and no manufacturer remedy is available. Unknown equipment means VHA has not been able to determine the compliance status of equipment because it has not received compliance status information from the manufacturer.

According to the August 1999 report, about 97 percent of the 568,000 medical devices in VHA medical facilities are compliant. The report indicated that, of about 18,000 noncompliant devices, about 14,000 will be repaired, and about 1,400 will be replaced. The report did not discuss the renovation status of the remaining 2,200 noncompliant devices.

We were unable to accurately determine the status of medical facilities' efforts to renovate noncompliant devices. As we discussed previously, the individual monthly reports submitted by the VISNs/medical facilities were inaccurate. Specifically, the July 1999 summary report that showed that about 21 percent of medical devices had been renovated was incorrect. However, according to several medical centers, their renovation percentages were higher than the numbers reflected in the report. We pointed this out to the Y2K project manager, who acknowledged that the percentages were incorrect. He added that the Y2K project office is in the process of following up with its medical centers to confirm their status on renovation of biomedical equipment.

VHA Position on Not Testing Biomedical Equipment Unchanged

As we reported last September, VHA relies on manufacturers to validate, test, and certify that equipment is Y2K compliant.[24] We also reported that there was no assurance that the

[24] GAO/AIMD-98-240, September 18, 1998.

manufacturers adequately addressed the Y2K problem for noncompliant equipment, because FDA did not require medical device manufacturers to submit test results to it certifying compliance. Accordingly, we recommended that VA and HHS take prudent steps to jointly review manufacturers' compliance test results for critical care/life support biomedical equipment. We were especially concerned that VA and FDA review test results for equipment previously determined to be noncompliant but now deemed compliant by manufacturers, or equipment for which concerns about compliance remain. We also recommended that VA and HHS determine what legislative, regulatory, or other changes were necessary to obtain assurances that manufacturers' equipment was compliant, including performing independent verification and validation of the manufacturers' certifications.

At that time, VA stated that it had no legislative or regulatory authority to implement the recommendation to review test results from manufacturers. VA and the Emergency Care Research Institute (ECRI) [25] have stated that manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. Accordingly, they do not encourage user testing of biomedical equipment for Y2K compliance. ECRI guidelines, however, suggest that health care facilities should consider testing interfaces between medical devices in cases where the facility cannot determine the Y2K compliance of the interface from the device manufacturer. FDA also agrees with the ECRI position on

[25] This institute is an international, nonprofit health services research agency. It believes that superficial testing of biomedical equipment by users may provide false assurances, as well as create legal liability exposure for health care institutions.

testing biomedical equipment and interface testing. Specifically, FDA has taken the position that manufacturers' submissions of Y2K compliance certifications provide sufficient assurance of product compliance, and that such testing on the part of users is not necessary.

According to VHA's chief biomedical engineer, VHA guidance to the VISNs and medical facilities is not to conduct stand-alone compliance testing of biomedical equipment in their inventories. VHA's Y2K project manager told us that VHA relies on the manufacturers' certifications; therefore, there is no need for such testing. However, he stated, in cases in which one medical device interacts with other systems or devices, the medical facilities should test these to ensure proper operation.

In contrast to VHA's and FDA's positions, some hospitals in the private sector believe that testing biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. As we have previously testified, officials at three hospitals told us that their biomedical engineers established their own test programs for biomedical equipment and, in many cases, contacted the manufacturers for their test protocols.[26] Several of these engineers informed us that their testing identified some noncompliant equipment that the manufacturers had earlier certified as compliant. According to these engineers, the equipment found to be noncompliant all had display problems; none was critical care/life support equipment. We were told that equipment found to be incorrectly certified as compliant included a cardiac

[26] GAO/T-AIMD-99-136, April 15, 1999.

catheterization unit, a pulse oxymeter, medical imaging equipment, and ultrasound equipment.

Our review of manufacturers' web sites disclosed that manufacturers' opinions vary on whether users should test their biomedical equipment.[27] We noted that at least 37 manufacturers provided information on their web sites about Y2K testing. Of these, 30 encouraged testing, and 15 of these 30 provided end-users with information such as test protocols and instructions. Fifteen of the 30 manufacturers also encouraged users to test their devices in configuration with related equipment to ensure that the device operated as intended. For example, the web site of a manufacturer of audiometers stated that "if your equipment is used in a critical application, we strongly advise you to test the equipment by simulating the millennium date change yourself." Seven of the 37 manufacturers did not encourage testing; two of these stated that such testing could disrupt operation of software.

Since some biomedical equipment manufacturers encourage end-user testing for Y2K compliance of their products, VA should reconsider its decision not to test equipment in those instances in which the manufacturer encourages users to test. Such action can provide greater assurance of Y2K compliance for those items. From an overall perspective, as we testified in April, the question of whether to independently verify and validate biomedical equipment that manufacturers have certified as compliant is one that must be addressed jointly by medical facilities' clinical staff, biomedical engineers, and

[27] *Year 2000 Computing Challenge: Compliance Status Information on Biomedical Equipment* (GAO/T-AIMD-00-26, October 21, 1999).

corporate management.[28] The overriding criterion should be ensuring patient health and safety.

VHA PHARMACEUTICAL OPERATIONS HAVE MADE PROGRESS IN ADDRESSING Y2K PROBLEM

Another critical component to VA's ability to deliver health care at the turn of the century is ensuring that the automated systems supporting VHA's medical facility pharmacies and its consolidated mail outpatient pharmacies (CMOPs) are Y2K compliant. VHA reported that in 1998 it filled about 72 million prescriptions for 3.4 million veterans, at an estimated cost of about $2 billion. About half of the prescriptions were filled by the over 200 pharmacies located at VA's medical centers, clinics, and nursing homes. These pharmacies rely on the pharmaceutical applications in their hospital information system for (1) drug distribution and inventory management, (2) dispensing of drugs to inpatients and outpatients, (3) patient medication information, and (4) an electronic connection between the pharmacies and the CMOPs.

The remaining half of VHA's prescriptions are filled by seven CMOPs, geographically dispersed throughout the United States. These facilities are supported by automated systems provided by one of two contractors—SI/Baker, Inc. and Siemens ElectroCom.[29] For example, the CMOP electronically receives a prescription for a veteran through the medical center. The prescription is downloaded to highly automated dispensing

[28] GAO/T-AIMD-99-136, April 15, 1999.
[29] These include operating systems, databases, and pharmacy fulfillment application software.

equipment to be filled. The filled prescription is then validated by a pharmacist who compares the medication against the prescription and a computerized image of the prescribed medication. Afterward, the prescription is packaged and an automatically-generated mailing label is applied for delivery to the veteran. Lastly, the medical center is electronically notified that the prescription has been filled.

As we testified this past April,[30] VHA had determined that the automated systems supporting its CMOPs were not Y2K compliant. Accordingly, the CMOPs' ability to fill prescriptions and process management reports could be delayed or interrupted if a Y2K failure occurred. At that time we also expressed concern about the mid- to late-1999 scheduled implementation of compliant systems.

Since our April testimony, VA's contractors have installed and tested compliant systems at all seven CMOPs. As shown in table 3, as of September 30, 1999, all seven CMOPs have reported their automated systems as compliant.

[30] GAO/T-AIMD-99-136, April 15, 1999.

Table 3: Actual Completion Dates for Implementing Compliant Systems and Current Daily Workload by Consolidated Mail Outpatient Pharmacies

Location	Actual Completion Date	Current Daily Workload (prescriptions filled)
Bedford, Massachusetts[a]	August 10, 1999	15,000
Dallas, Texas[a]	August 10, 1999	14,000
West Los Angeles, California[a]	September 8, 1999	15,000
Leavenworth, Kansas[a]	September 30, 1999	16,000
Murfreesboro, Tennessee[b]	September 22, 1999	38,000
Charleston, South Carolina[b]	September 26, 1999	23,000
Hines, Illinois[b]	September 26, 1999	21,000

[a]Siemens ElectroCom automation
[b]SI/Baker, Inc. automation

Source: VA.

We also testified in April that it was crucial that the CMOPs develop business continuity and contingency plans to ensure that veterans will continue to receive their medications should the CMOPs experience a Y2K-related failure. On September 3, 1999, the national CMOP director approved the Consolidated Mail Outpatient Pharmacy Year 2000 Contingency Plan which (1) defines the responsibilities of the national director, the local CMOP director, the national Y2K coordinators, the local Y2K coordinators, and the business resumption team; (2) establishes procedures for preparing and implementing the contingency plan and implementing it during the execution phase; and (3) provides a schedule of critical events and a time line for actions to be taken during the execution phase.

In addition, each of the seven CMOPs drafted contingency plans addressing core business processes. These plans, along with the Y2K Mail Transfer Contingency Test Procedures, which are the necessary steps relating to loss of the wide area network, were forwarded to the medical centers serviced by each CMOP during July and August of this year. Each medical center was asked to certify that the CMOP contingency plan had been reviewed and will be incorporated into the medical center's Y2K contingency plan. However, according to the national CMOP Y2K coordinator, as of October 25, 1999, about half of the medical facilities had not returned their certifications.

According to the CMOP Y2K plan, the CMOPs are expected to completely test their plans by the end of October. Five CMOPs participated in a live test last month. Specifically, anticipating a direct hit from Hurricane Floyd, the Charleston CMOP reallocated the prescriptions for its 21 medical centers to four other CMOPs— Bedford, Dallas, Hines, and West Los Angeles. The Charleston CMOP lost 36 hours of production time, and 55,683 prescriptions had to be processed by the other CMOPs.

VA Continues Efforts to Determine Y2K Readiness of Pharmaceutical and Medical-Surgical Manufacturers

Like other users of pharmaceutical and medical-surgical products, VA needs to know whether it will have a sufficient supply of these items for its customers. Therefore, it has taken a leadership role in the federal government in determining whether manufacturers

supplying these products to VHA are Y2K-ready. This information is essential to VHA's medical facilities and CMOPs because of their "just-in-time"[31] inventory policy. Accordingly, they must know whether their manufacturers' processes, which are highly automated,[32] are at risk, as well as whether the rest of the supply chain will function properly.

We testified in April that VA's National Acquisition Center [33] sent a survey on January 8, 1999, to 384 pharmaceutical firms and 459 medical-surgical firms with whom it does business to determine their Y2K readiness.[34] The survey contained questions on the firms' overall Y2K status and inquired about actions taken to assess, inventory, and plan for any perceived impact that the century turnover would have on their ability to operate at normal levels. In addition, the firms were requested to provide status information on progress made to become Y2K compliant, and a reliable estimated date when compliance would be achieved for business processes such as (1) ordering and receipt of raw materials, (2) mixing and processing product, (3) completing final product processing, (4) packaging and labeling product, and (5) distributing finished product to distributors/wholesalers and end customers.

[31] This term refers to maintaining a limited inventory on hand.
[32] Many pharmaceutical manufacturers rely on automated systems for production, packaging, and distribution of their products, as well as for ordering of raw materials and supplies.
[33] This organization is responsible for supporting VHA's health care delivery system by providing an acquisition program for items such as medical, dental, and surgical supplies and equipment; pharmaceuticals; and chemicals. The National Acquisition Center is part of VA's Office of Acquisition and Materiel Management.
[34] Five additional firms were identified from survey responses received after April 1999.

In March the acquisition center sent a second letter to its pharmaceutical and medical-surgical firms, informing them of VA's plans to make Y2K readiness information previously provided to VA available to the public through a web site (www.va.gov/oa&mm/nac/y2k). VA made the survey results available on its web site on April 13, 1999.[35] The letter also requested that manufacturers that had not previously responded provide information on their readiness. The acquisition center's executive director said that he would personally contact any major VA supplier that did not respond.

According to an August 1, 1999, briefing report on their survey, the acquisition center reclassified the 517 companies that responded to the survey into three categories: "pharmaceutical firms,"[36] "pharmaceutical, other firms,"[37] and "medical-surgical firms." As shown in table 4, as of August 1, 1999, the latest available date from VA, about one-third of the pharmaceutical firms, a little over one-third of the "pharmaceutical, other" and almost 44 percent of the medical-surgical firms had not responded to the survey.

[35] This site identified the firms that were sent surveys and those that responded.
[36] Firms that manufacture and distribute both pharmaceuticals and medical/surgical are included in the pharmaceutical category.
[37] Pharmaceutical firms that also manufacture and distribute medical gases and reagents (substances used in chemical reactions to detect, measure, examine, or produce other substances).

Table 4: Status of Companies Surveyed by VHA as of August 1, 1999

Responses	Pharmaceutical	Pharmaceutical, other	Medical-surgical
Y2K compliant	55	28	146
Will be compliant by 1/1/2000 or earlier[a]	92	30	79
Provided no compliance date	39	14	34
Total number of responses	186	72	259
Non-responses	90	40	201
Total number of firms surveyed	276	112	460

[a]Estimated compliance status date ranged from 3/31/99 through 1/1/2000; about 72 percent of all respondents estimated they would be compliant by 7/31/99. One firm responded that it would be compliant by 1/01/2000.

Source: VA. We did not independently verify these data.

To determine if all respondents who had initially provided an anticipated compliance date of July 31, 1999, or earlier had met this date, a follow-up survey was sent to 140 firms on July 20, 1999. As shown in table 5, as of October 26, 1999, about two-thirds (64 percent) responded to the survey. A little over half of the respondents (52 percent) completed the survey, while the remaining respondents forwarded company letters, Year 2000 readiness disclosure statements, and company financial statements with disclosures on Y2K readiness. Table 5 also shows that about half of the respondents did not meet the targeted date of July 31, 1999; almost 84 percent, however, anticipate full compliance by September 30, 1999. The results of this follow-up survey are not currently available on VA's web site.

Table 5: Status of Companies with July 31, 1999, Or Earlier Anticipated Compliance Date as of October 26, 1999

	Number of Firms	Percentage
Total number of surveys distributed	140	100
Number of responses	90	64
Firms completing survey	47	52
Were compliant by 7/31/99	25	53
Anticipate compliance by 9/30/99	19	40
Anticipate compliance by fourth quarter	3	6
Firms forwarding company letters, etc.	43	48
Were compliant by 7/31/99	17	40
Anticipate compliance by 9/30/99	14	32
Anticipate compliance by fourth quarter	3	7
No date furnished	9	21

Source: VA. We did not independently verify these data.

On a broader level, VHA has taken a leadership role in obtaining and sharing information on the Y2K readiness of the pharmaceutical industry. Specifically, VHA chairs the Year 2000 Pharmaceuticals Acquisitions and Distributions Subcommittee, which reports to the Chair of the President's Council on Year 2000 Conversion. The purpose of this subcommittee is to bring together federal and pharmaceutical representatives to address issues concerning supply and distribution as it relates to the year 2000. The subcommittee consists of representatives of FDA, federal health care providers, and industry trade associations such as the Pharmaceutical Research and Manufacturers of America, the National Association of Chain Drug Stores, and the National Wholesale Druggists' Association. Several of these trade associations have surveyed their members on their Y2K readiness and have made the results available to the public. Further, the

Pharmaceutical Alliance for Y2K Readiness[38] announced on September 22, 1999, that consumers will have access to a substantial supply of medications during the Y2K date change and there should be no need for consumers to overbuy medications in preparation for Y2K.

The executive director of the National Acquisition Center told us that, based on his interactions with the trade associations, as well as results received from manufacturers, he is confident that there will be no shortage of medication and medical-surgical supplies. He explained that the major companies with unique drugs that VA relies on have responded that they will be ready and have provided the necessary resources and management attention. Further, he said, all ten of VA's largest pharmaceutical and medical-surgical suppliers have responded to the survey and have taken actions to address the Y2K problem at their firms. Accordingly, the executive director does not plan to take any further action, including following up with those manufacturers that did not meet their anticipated compliance date of July 31, 1999, or September 30, 1999.

We believe that VHA needs to continue to follow up with pharmaceutical and medical-surgical firms that anticipated having compliant systems by July 31, 1999, and September 30, 1999, to determine whether these firms have addressed the Y2K problem. This information should also be made available on VHA's web site.

[38]A coalition of drug manufacturers, wholesale distributors, pharmacies, and health care organizations that are working closely with government agencies to ensure a continued and substantial supply of pharmaceuticals through January 1, 2000.

FDA'S Y2K ACTIVITIES ON BIOMEDICAL EQUIPMENT AND PHARMACEUTICAL, BIOLOGICAL, AND CONSUMABLE MEDICAL PRODUCTS INDUSTRIES ARE FOCUSED ON READINESS

Another key player in determining the Year 2000 compliance of biomedical equipment and pharmaceutical, biological, and consumable medical products is FDA, which has oversight and regulatory authority in these areas. FDA's role is to ensure that these products are safe and effective for public use. In an effort to provide users with Y2K compliance information on their equipment, FDA has established the Federal Y2K Biomedical Equipment Clearinghouse. In addition, it has surveyed manufacturers of pharmaceutical, biological, and consumable medical products, to provide users with information on their Y2K readiness.

Biomedical Equipment Status Information Available Through FDA Clearinghouse

We reported in September 1998 that FDA was working to determine the compliance status of biomedical equipment; provide a comprehensive, centralized source of information on the Y2K compliance status of biomedical equipment used in the United States; and make this information publicly available on a web site.[39] However, we also reported that FDA's database did not include product compliance information from many

[39] GAO/AIMD-98-240, September 18, 1998.

manufacturers that had already provided such information to VHA, and also that VHA was not making this information available to the public. We therefore recommended that HHS and VHA jointly develop a single data clearinghouse containing information on the Y2K compliance status of biomedical equipment, and make this information publicly available. In response to our recommendation, FDA—in conjunction with VHA—established the Federal Y2K Biomedical Equipment Clearinghouse. In obtaining compliance status information from manufacturers, VHA, the Department of Defense, and the Health Industry Manufacturers Association all assisted FDA.

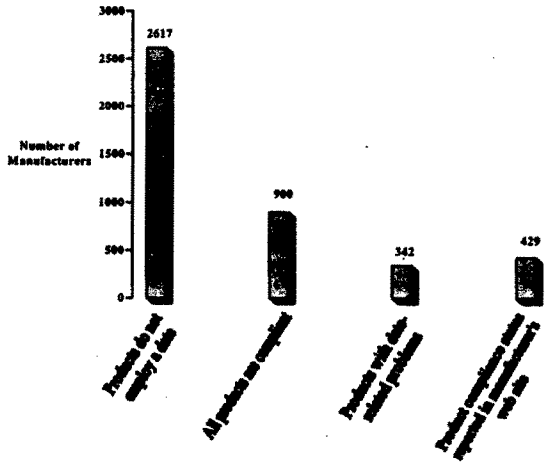
We testified last week that, according to FDA, 4,288 biomedical equipment manufacturers had submitted data to the clearinghouse as of October 4, 1999.[40] Based on the data submitted, FDA places a manufacturer into one of four categories:

- Products that do not employ a date—manufacturer that reported Y2K status to be "All Products Do Not Use a Date."
- Products that are all compliant—manufacturer that reported products as Y2K compliant.
- Products with date-related problems—manufacturer that reported its Y2K status to be "Products With Date Related Problem."
- Product status is on the manufacturer's web page—manufacturer that reported its Y2K status to be "Product Status Specified on a (Web) Page."

[40] GAO/T-AIMD-00-26, October 21, 1999.

As shown in figure 1, as of October 4, 1999, 61 percent of the manufacturers reported having products that do not employ a date, while 8 percent (342 manufacturers) reported having date-related problems such as incorrect display of date/time. According to FDA, the 342 manufacturers reported 1,035 specific products with date-related problems.

Figure 1: Biomedical Equipment Compliance-Status Information Reported to FDA by Manufacturers as of October 4, 1999.



Note: Total number of manufacturers = 4,288.

Source: FDA.

Also, according to FDA, as of October 4, 1999, 132 manufacturers had not responded to the agency's request for product compliance information. A senior FDA official told us that most of these manufacturers have gone out of business, do not make computerized products, or just cannot be located. The official added that FDA continues to follow up with these manufacturers nevertheless, through letters and telephone contact. The clearinghouse lists the names of these manufacturers that have not responded to FDA's requests for product compliance information.

In our September 1998 report, we also noted that information on the FDA web site was not detailed enough to be useful.[41] Specifically, the list of compliant equipment contained no information on the equipment's make and model. We therefore recommended that VA and HHS include in the clearinghouse information on the compliance status of all biomedical equipment by make and model. FDA agreed with this recommendation, and subsequently requested this information from manufacturers; users can now find specific information on the make and model of compliant medical devices on the FDA web site.

As an alternative to obtaining biomedical equipment product compliance information from manufacturers and posting it to the Federal Y2K Biomedical Equipment Clearinghouse, FDA accepts equipment manufacturers' references to their own web sites

[41] GAO/AIMD-98-240, September 18, 1998.

for compliance information. The clearinghouse provides users with a link directly to these web sites. As of October 4, 429 manufacturers had chosen this option.

While FDA is aware of the number of products and their reported compliance status for those manufacturers providing this information to the Federal Y2K Biomedical Equipment Clearinghouse, in testimony this past May FDA officials stated that they did not know the total number of biomedical equipment products reported by manufacturers on their web sites, or how many of them were noncompliant. We subsequently reviewed information available through these web sites and reported in June that the quality of information available through them varied significantly.[42] Specifically, we found that while most sites contained compliance information on at least one product, some sites contained insufficient information or did not clearly distinguish biomedical equipment from nonbiomedical products.

We subsequently updated our analysis of the web sites as of October 1, 1999, and found the following for the 429 manufacturers in FDA's clearinghouse that refer users to their web sites:

- 354 manufacturers reported compliance status information for at least 33,598 individual biomedical equipment products,[43]

[42] *Year 2000 Computing Challenge: Concerns About Compliance Information on Biomedical Equipment* (GAO/T-AIMD-99-209, June 10, 1999).

[43] This includes medical devices and scientific and research instruments, and other supporting products, such as printers and software.

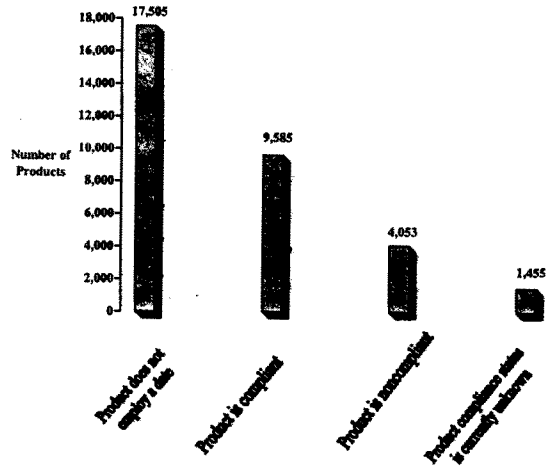
- 71 manufacturers' web sites either contained insufficient information on the number of products and their compliance status, or did not clearly distinguish biomedical equipment from nonbiomedical products,
- 3 web sites were those of vendors or distributors, not manufacturers, and
- 1 manufacturer's web-site link in FDA's clearinghouse did not work,[44]

Because of the limitations cited above for many of the manufacturers' web sites, our ability to determine the total number of biomedical equipment products reported and their compliance status was limited. Accordingly, the actual number of products reported by these manufacturers could be higher than the 32,598 that we counted.

As shown in figure 2, of the 32,598 products we identified on manufacturers' web sites, about 54 percent reportedly do not employ a date, about 29 percent of the products are considered compliant, and about 12 percent are reportedly noncompliant. The compliance status of the remaining 5 percent of products was unknown for reasons such as the manufacturer's ongoing assessment of the product.

[44] According to FDA, the contractor assisting it with the clearinghouse verified that this web site link was operable.

Figure 2: Biomedical Equipment Compliance-Status Information Reported on Manufacturers' Web Sites as of October 1, 1999.



Note: Total number of products = 32,598.

Source: GAO analysis of manufacturers' web sites.

The 4,053 noncompliant products that we identified were from the web sites of 214 manufacturers. This number of products is about four times the number reported directly by FDA in its clearinghouse (1,035). Examples of these noncompliant products included a bedside monitor, film digitizer, ultrasound systems, radiology information systems, and

laboratory information systems. Included among noncompliant potentially high-risk devices reported were ventricular assist devices and hemodialysis equipment.[45]

In addition to supplying information on noncompliant products, most of the manufacturers with noncompliant products also provided solutions to correct the problem. Most (190) of the 214 manufacturers identified with noncompliant products provided at least one solution to correcting the problem. The solutions generally involved upgrades to hardware or software, manual action (such as turning the equipment on and off on January 1, 2000), or workarounds.[46]

FDA Is Now Reviewing
Manufacturers' Y2K Activities

While compliance information is available through FDA's Federal Y2K Biomedical Equipment Clearinghouse, we have raised concerns in the past year about the lack of independent verification and validation of biomedical equipment that manufacturers have certified as compliant. In addition to making sure that manufacturers provide detailed information on their products, we believe that it is essential that FDA provide some level of confidence that critical care and life support medical devices will work as intended.

[45] A ventricular assist device is a small electromechanical pump that helps maintain blood circulation in patients suffering from end-stage heart disease. Hemodialysis equipment cycles blood from a patient's body to filter out body waste before returning the blood to the patient.
[46] An example of a workaround is noting on the printout of an EKG machine the year "2000" instead of "1900."

In response to our recommendation to conduct independent verification and validation of biomedical equipment that manufacturers have certified as compliant, FDA is taking action to review a sample of biomedical equipment manufacturers' Y2K activities, such as risk management, test planning and procedures, and implementation and contingency planning. Specifically, FDA's acting deputy commissioner for policy testified in May 1999 that FDA proposed reviewing manufacturers' test results supporting their compliance certifications for a sample of critical devices. FDA's proposal consisted of two phases. In the first phase FDA would

- develop a list of the manufacturers of computer-controlled, potentially high-risk devices (PHRD);[47]
- from this list of manufacturers, select a sample of 80 manufacturers for review; and
- hire a contractor to develop a program to assess manufacturers' activities to identify and correct Y2K problems with PHRDs.

The goal of the first phase of the survey is to extrapolate from the 80 assessments a level of overall confidence in the biomedical equipment industry's Y2K compliance activities. According to FDA, the second phase of the evaluation would be undertaken only if the results of the first phase indicated a need for further review of manufacturer Y2K activities because of concerns over how manufacturers are addressing product compliance.

[47] These medical devices are characterized by their potential for immediate and serious adverse health consequences for a patient if they fail to function as designed or expected, including a failure to initiate or continue operations.

In carrying out its plan to assess manufacturers' Y2K activities, FDA identified 90 types of PHRD products, and issued a task order on July 1, 1999, for a contractor, assisted by two subcontractors, to perform assessments of the Y2K compliance activities for a sample of PHRD manufacturers. FDA identified 803 PHRD manufacturing sites that produce equipment sold in the United States.[48] These were comprised of 726 biomedical equipment manufacturing sites and 77 manufacturing sites of blood and blood products equipment.

FDA's contractor then randomly selected 325 of the 803 sites for possible assessment. These manufacturing sites were then contacted and asked if they would volunteer to participate in the process. As of October 4, 1999, of the 325 randomly selected sites,

- 197 were identified as producing no computer-controlled equipment,
- 80 agreed to participate,
- 26 declined to participate,[49]
- 18 were duplicates,[50] and
- 4 did not respond.

To carry out the on-site assessments of manufacturing sites, the contractor developed a guide for its examiners. This guide focused on the firm's Y2K activities in six areas: (1) executive leadership and control, (2) risk management, (3) corrective and preventive

[48] The 803 consisted of those manufacturers that had registered PHRD products with FDA that were among the 90 types of PHRDs identified.
[49] Reasons given by manufacturers for declining to participate included scheduling or resource limitations, and recent regular FDA site inspections. Five manufacturing sites declined without giving a reason.
[50] These sites involved large, multi-site manufacturers where the FDA contractor had already selected two or more of the manufacturer's sites. According to FDA, the contractor did not assess duplicates if they came up in later samples.

actions, (4) test planning and procedures, (5) communication with the consignee (user of the products), and (6) implementation and contingency planning.

After completing these assessments, examiners were required to prepare a report of concerns in each of the six areas reviewed at each manufacturing site. Concerns were identified as high, medium, or low, as defined below:

- high—relates to actions that are not timely, inadequate planning, inadequate or incomplete resources, incomplete or inaccurate deliverables, unable to validate results, and/or inadequate due diligence;
- medium—relates to actions that are somewhat late, incomplete planning, insufficient or incomplete resources, deficiencies in deliverables, and/or incomplete validation of results; and
- low—relates to actions that are on schedule, and have adequate resources.

According to FDA's PHRD survey project manager, as of October 15, 1999, examiners had completed all 80 manufacturer site assessment visits, and had prepared 62 assessment reports.

We reviewed the 25 manufacturer site visit reports that were completed by the examiners and available to us as of September 10, 1999. For 20 of these assessments, concern was low. At the five remaining sites, the examiner assessed at least one concern as moderate in one of the six areas, such as test planning and procedures. According to the FDA

PHRD survey project manager, the areas identified in the site visit reports as medium risks do not constitute a risk to patient health or safety.

Until recently, none of the site visit reports submitted to FDA contained a concern assessed as high. However, last week, the PHRD survey project manager informed us that FDA had received a site visit report with concerns accessed as high in two areas—leadership and control, and test planning and procedures. The report stated that the manufacturer's polices and procedures were found to be inconsistent, ambiguous, and were not followed in a manner that would meet due diligence requirements. It also noted that the qualifications of the manufacturer's personnel for specified tasks were not well defined, and that some personnel assigned to tasks identified in the policies and procedures were not qualified to perform those tasks. The report concluded that the manufacturer's procedures for Y2K assessment and corrective and preventive action were less than adequate, and that assessment procedures had not been applied consistently. The manufacturer subsequently told the examiner that action would be taken on the issues raised.

Late last week, FDA's Senior Associate Commissioner for Policy, Planning, and Legislation testified that FDA sent an inspector to follow up with this manufacturer. The FDA official said the inspector determined that the deficiencies noted would not affect patient safety. He also stated that FDA would continue to monitor the situation at this site.

Regarding the overall planned phase one report, the project manager told us that FDA's contractor is in the process of preparing a final report summarizing the findings from the 80 site visit assessment reports, detailing any problems encountered during the project and recommending whether the second phase should be performed. Although FDA initially expected to submit a final report to HHS by October 1, it has not yet established a revised deadline. Accordingly, it does not know when this information will be made available to the public. We believe that this information should be made available as soon as possible.

To assess how the contractor was executing FDA's task order, we observed selected site visit assessments. At the five manufacturing site assessments we observed, the examiners generally followed the contractor-developed audit guide, and were knowledgeable about information technology management, Y2K testing, and risk assessment. During our two initial visits, we noted that the examiners sometimes could not answer questions from the manufacturers relating to the FDA clearinghouse and the processing of the final report on the site assessments. We subsequently shared these observations with FDA official, who agreed to consider our suggestions, such as better communicating to the firms the final reporting process and how the FDA Federal Y2K Biomedical Clearinghouse works. During the later three visits, we did not observe any similar areas of concern.

FDA's Activities to Determine Y2K Readiness of Manufacturers of Pharmaceutical, Biological, and Consumable Medical Products

FDA's oversight and regulatory responsibility for pharmaceutical, biological, and consumable medical products[51] is to ensure that they are safe and effective for public use. Since our April testimony,[52] FDA has taken action to determine the Y2K readiness of these industries. Specifically, FDA is conducting voluntary surveys of manufacturers of pharmaceutical, biological, and consumable medical products for Y2K readiness. These surveys assess manufacturers' plans and preparations to continue operations after January 1, 2000.

According to FDA's Senior Associate Commissioner for Policy, Planning and Legislation, information obtained from these surveys thus far indicates that there will likely be no significant disruption of necessary supplies of pharmaceuticals, biologicals, or consumable medical products as a result of Y2K. FDA believes that essential medical supplies will be available, and that the drug supply will be safe and adequate.

To obtain information on the Y2K readiness of the pharmaceutical industry, on April 21, 1999, the FDA commissioner sent a letter to the presidents and CEOs of approximately 4,228 pharmaceutical manufacturers that produce prescription drugs, over-the-counter medication, bulk drugs, and also to drug distributors and repackagers, and medical gas

[51] Biological products include vaccines, blood, and blood products.
[52] GAO/T-AIMD-99-136, April 15, 1999.

manufacturers. In the letter, the commissioner requested the assistance of these firms in assuring the American public that the firms had addressed the Y2K problem as it affects the adequacy, safety and effectiveness of the supply of pharmaceuticals in the United States.

According to FDA's Senior Associate Commissioner for Policy, Planning, and Legislation, as of October 8, 1999, 3,132 (74 percent) of the firms had responded to the survey. Of these, 95 percent stated that they would be Y2K ready by October 31, 1999. According to the senior associate commissioner, FDA is committed to maximizing the response, especially from the 274 priority manufacturers who produce sole source, orphan drugs,[53] or the top 200 prescribed medications.

This FDA official testified on October 21, 1999, that, in addition to conducting the survey of pharmaceutical manufacturers, distributors, etc., FDA is taking the additional step of obtaining independent assurance of these firms' Y2K assessments and corrections. The agency has obtained a contractor that is auditing each of 160 highest priority pharmaceutical firms, as well as a random sample of other firms. As of October 8, 1999, 88 percent of these assessments have been completed. The report stated that the results of their audits to date are positive and confirmed FDA's expectation that the

[53] Orphan drugs are those produced under provisions of the Orphan Drug Act (P.L.97-414, § 983, as amended). The act provides incentives for manufacturers to produce drugs that are used by a small number of patients to treat a specific, but not widespread, medical condition.

pharmaceutical industry has taken the necessary steps to prepare for the year 2000. The interim report[54] is available on FDA's web site.[55]

FDA is also assessing the Y2K readiness of the biologics industry. In June, the Center for Biologics Evaluation and Research mailed a survey on Y2K readiness to 1,576 licensed biologics manufacturers and registered blood establishments. FDA also sent letters to biologics trade organizations requesting their assistance in encouraging their members to participate in the survey.

According to FDA's senior associate commissioner, as of October 15, 1999, it had received responses from 1,483 (94 percent) of the licensed manufacturers and blood establishments. In addition, as with the pharmaceutical industry, FDA is conducting follow-up audits of 110 high-priority firms to assess their Y2K readiness. To date, FDA reports finding no problems with the audited firms. In addition, FDA is conducting random audits of other firms, and has completed audits of 48 of these with no problems identified as of October 14, 1999. FDA told us on October 27 that it plans to publicize the survey and audit results of the biologics manufacturers, although it has not established a date when this information will be available. We believe that this information should be made available as soon as possible.

[54] *Center for Drug Evaluation and Research's Interim Report: Assessment of the Pharmaceutical Industry's Readiness for Year 2000*, FDA, October 18, 1999.
[55] The site is located at http://www.fda.gov/cder/y2k.

FDA also mailed Y2K readiness surveys to 3,070 manufacturers of consumable medical supplies in June.[56] This survey focused on manufacturers that produce critical devices that are used and consumed on a recurring basis during the delivery of essential health care services, as well as those whose availability is critical to the uninterrupted delivery of health care and patient welfare. As of October 14, 1999, FDA had received 2,074 responses (68 percent) to its survey. According to FDA's senior associate commissioner, approximately 90 percent of these respondents report that they will be ready for Y2K by October 31, 1999.

FDA is also conducting audits of firms that supply medical consumables. It has given highest priority to 225 firms that produce devices that are only manufactured by a handful of those firms, as well as 57 manufacturers that are sole-source suppliers. According to FDA's senior associate commissioner, to date, 197 of the high-priority firms have responded, and 48 of the 57 sole-source firms have responded. On October 27, 1999, FDA told us that it plans to make the detailed survey and audit results for consumable medical products manufacturers available to the public, but it has not yet determined the date when this will be done. We believe that it is critical to make this information available.

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In summary, VA has made much progress in addressing the Y2K computer problem. However, some critical tasks remain in the areas of testing business continuity and

[56] Consumable medical supplies include such items as intravenous tubing, kidney dialysis filter units, and blood and blood product bags.

contingency plans and reporting Y2K compliance status of key components such as facility systems at VHA medical facilities. VHA should also reassess its decision not to test biomedical equipment in those instances in which the manufacturer encourages such testing. Additionally, VA needs to continue to follow up with pharmaceutical and medical-surgical firms that anticipated having compliant systems by July 31, 1999, and September 30, 1999, respectively, and make this information available to the public through its web site.

Compliance status information on biomedical equipment can now be found in FDA's clearinghouse or on manufacturers' web sites. Also, to its credit, FDA has assessed the Y2K compliance activities of some PHRD manufacturing sites. This information should provide the American public with a higher level of confidence that medical devices will work as intended. FDA now needs to finalize its overall report on the results of its review of the PHRD manufacturing sites, and make this information available to HHS and the public through its web site.

We performed this assignment in accordance with generally accepted government auditing standards, from May through October 1999. In carrying out this assignment, we reviewed and analyzed VA's Y2K documents and plans, comparing them against our guidance on Y2K activities. More specifically, we observed VBA's "dry run" testing of its benefits payment systems, VHA's forward-date tests of its hospital information

systems, and tests of CMOP Y2K fixes. We reviewed the test plans, selected test scripts, and test results for each Y2K test. We also reviewed business continuity and contingency plans for a sample of for VHA medical centers and VBA regional offices, as well as VBA data centers. In addition, we reviewed and analyzed FDA documentation relating to its Y2K efforts on biomedical devices and pharmaceutical manufacturers. More specifically, we identified the amount and quality of information on product compliance information available on biomedical equipment manufacturers' web sites, reviewed information from those sites to identify the total number of biomedical equipment products reported, and categorized their compliance status.[57] We also reviewed manufacturers' web sites to assess the clarity and completeness of the information reported.

In addition, we visited selected VHA medical centers, VBA regional offices, VA data centers, and VHA consolidated mail outpatient pharmacies to discuss their Y2K activities, and interviewed VA and FDA officials about those activities. Finally, we interviewed selected private hospital officials about their Y2K actions and pharmaceutical trade associations on their Y2K readiness surveys of pharmaceutical manufacturers.

[57] We summarized the results of our review in four compliance categories—products that do not employ a date, products that are compliant, products that are noncompliant, and products whose compliance status is currently unknown. This last category includes those manufacturers who reported that they have not completed an assessment of their products, have discontinued a product, or have a product that is now obsolete.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions that you or other members of the Subcommittee may have at this time.

Contact and Acknowledgments

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(511757)

STATEMENT BY

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SENIOR ASSOCIATE COMMISSIONER
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FOOD AND DRUG ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

OCTOBER 28, 1999

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, my name is William K. Hubbard. I am the Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration (FDA or the Agency). I am pleased to be here today to provide an update on the Year 2000 (Y2K) date issue as it relates to medical devices, drugs and biologics. In April of this year, I appeared before the Committee and discussed with you the need for FDA to allay the fears of the American public whether life-sustaining medical devices will function as intended and whether there will be a sufficient supply of high priority pharmaceuticals due to Y2K issues. At that time, I told you that we were optimistic that the industries were taking the necessary steps to guard against Y2K breakdowns. Now that it is October and the year 2000 draws near, I am here today to tell you about FDA's efforts to validate our optimism.

FDA stepped up its efforts to gather more information on the Y2K readiness from industry through additional surveys and audits. This additional data provides FDA with a high degree of confidence in assuring the health care community and the American public that essential medical supplies will be available; and medical devices will function as intended; and that there will be a safe and adequate supply of drugs available. The Agency's efforts to obtain additional data and the high degree of confidence we have today is a tribute to the collaborative efforts among the Federal sector, healthcare community and industry. Let me summarize for you the Agency's efforts.

Y2K STATUS OF BIOMEDICAL DEVICES

FDA has taken a number of steps to enhance the confidence of the American public that medical devices will function as intended as the year 2000 approaches. For the past two years, FDA has continued to add to its knowledge of the Y2K status of medical devices and to make this information available to healthcare facilities. In developing this high level of confidence FDA has taken a number of constructive actions to work with manufacturers and provide information to users about the Y2K compliance of medical devices.

FDA's Y2K DATABASE

An important tool for obtaining information about biomedical equipment is FDA's Federal Year 2000 Biomedical Equipment Clearinghouse database. It is available via the World Wide Web at www.fda.gov. While the database has proven to be useful to healthcare facilities, professionals and consumers -- receiving over 236,691 "hits" from 197,461 users over a period of 17 months -- FDA has continued to collect information from medical device manufacturers. FDA believes that approximately 2,300 of the 16,000 biomedical equipment manufacturers could produce equipment that could be affected by the Y2K problem. The vast majority of these 2,300 manufacturers have responded to FDA's requests for Y2K status information, and every effort is being made to locate the remaining companies.

SURVEYS AND ASSESSMENTS

To bolster public confidence in industry's efforts to identify and resolve Y2K problems and to assure a continued supply of needed pharmaceuticals, biologics and essential medical supplies, FDA conducted a voluntary survey of manufacturers of drugs, biologics and consumable medical devices for Y2K readiness. These surveys assessed manufacturers' preparations and plans to continue operations after January 1, 2000. FDA then audited the survey results for a sample of the firms, as well as a high proportion of high priority firms to confirm the survey reports. These surveys indicate that the regulated industries have devoted considerable efforts to Y2K preparations and we do not expect significant interruptions of necessary supplies.

POTENTIALLY HIGH RISK DEVICES (PHRDs)

Although FDA firmly believes that its normal regulatory processes provide the necessary assurances that Y2K problems with high-risk devices will be carefully addressed, FDA implemented a plan to provide additional assurance to the public and healthcare facilities about the Y2K status of medical devices. FDA addressed concerns about the adequacy of the medical device industry's actions taken to avoid serious Y2K problems by independently validating their Y2K self-assessments.

FDA developed and posted on the FDA Y2K website a list of types of potentially high risk devices (PHRDs) that are likely to be computer-controlled and that could present a significant risk of immediate harm to the patient should the devices fail to operate as expected due to a Y2K problem. The PHRDs list contains 90 types of potentially high-risk devices for which FDA has identified 803 PHRDs manufacturers. An FDA contractor contacted these 803 firms

and learned that approximately 60 percent have no computerized devices.

FDA initiated a special study designated as a "Special Year 2000 Data Gathering Request" to examine the Y2K programs of a random sample of potentially high-risk device (PHRD) manufacturers. Eighty of the PHRDs manufacturers were randomly selected for an on-site assessment by an FDA contractor with extensive experience in information technology and Y2K verification and validation. The study was designed to:

- provide a high level of assurance that manufacturers have properly assessed the Y2K status of their computer-controlled medical devices;
- examine manufacturers' processes to evaluate how they assess the Y2K status of their products;
- verify that the manufacturers have developed and properly validated appropriate upgrades to correct any Y2K problems for these devices; and,
- confirm the information provided by manufacturers for the Federal Year 2000 Biomedical Equipment Clearinghouse database by examining the supporting documentation of the manufacturers.

RESULTS OF PHRDs ASSESSMENTS

As of October 15, 1999, the contractor has completed all 80 on-site reviews of records to assess the existence and adequacy of manufacturers processes and procedures implemented under a quality system. The assessments are intended to assure that potentially vulnerable devices have been adequately assessed and that upgrades are correctly implemented and appropriately tested and evaluated by the manufacturer. As part of this process, FDA is evaluating the reports as they are completed and to date has found no serious problems related to Y2K. The contractor will provide FDA with a final report of the assessments in early November. FDA will review the contractor's report and will issue a summary report in early November. FDA is confident that the evaluation of these manufacturers will demonstrate the thoroughness with which manufacturers have assessed and provided information and corrections for non-compliant products.

Now that manufacturers should have completed their assessments of Y2K compliance status and identified non-compliant devices, FDA will review this information to identify any manufacturers of PHRDs for which information is not available, or whose non-compliant products pose an actual significant risk to patient health. For firms that have declined to voluntarily participate in the PHRDs assessments, if these firms have not been inspected recently by FDA, the Agency will consider by the middle of November whether an FDA inspection of the firm should be conducted, based on the possible level of risk that the product may present. In these situations, FDA will review the steps taken by the manufacturers to notify users regarding any problems that might exist and to assure that appropriate corrections are implemented.

In any case where the action by the manufacturer has been inadequate to assure patient safety, FDA will use its statutory authorities to require corrections and publicize

the situations. FDA is prepared to take action which would include public advisories to device users, suggestions to manufacturers regarding voluntary recalls, mandatory recalls or seizure of the non-compliant devices in extreme risk situations. FDA expects, however, that the situations where such actions will be required will be rare as there are many incentives in addition to possible FDA regulatory action which lead manufacturers to address any such potentially high risk situations before FDA regulatory action is needed.

PHARMACEUTICAL INDUSTRY AND Y2K COMPLIANCE

FDA also has been examining the intersection of Y2K risk mitigation and the availability and quality of certain prescription drugs. In fact, government agencies and organizations within the pharmaceutical industry supply system (including manufacturers, distributors, pharmacies, hospitals, physicians, pharmacists, insurers and others) have been working closely together to prepare for the year 2000 date change and its potential impact on the supply of pharmaceuticals.

In an effort to obtain additional data on this issue, on April 21, 1999, the FDA Commissioner, Dr. Jane E. Henney, sent a letter to the Presidents and CEOs of approximately 4,228 pharmaceutical manufacturers, which includes prescription, over-the-counter, and bulk drug manufacturers; distributors-repackagers; and, medical gas manufacturers. The letter requested their assistance in assuring FDA and the American public that their firms have addressed the Y2K problem as it affects the adequate supply of safe and effective drugs. Included with the letter was a "Y2K Assessment Survey" concerning the status of actions pharmaceutical firms have taken to address this issue and assess Y2K readiness within the pharmaceutical industry. The focus of this effort is on prescription products with emphasis on the priority firms (sole source, orphan and the top 200 prescribed products).

Survey of Pharmaceutical Manufacturers

As of October 8, 1999, 3,132 or 74.1 percent responded to the survey, including 1,053 of the 1,070 or 98 percent of the prescription drug manufacturers that were surveyed. Of the approximately 274 priority manufacturers (160 - excluding subsidiaries) which includes sole source, orphan and top 200 prescribed, 270 or 99 percent have responded. Of the firms that completed the survey, 95 percent state they will be ready for Y2K by the end of October with both the foreign and domestic firms having a similar pattern of Y2K readiness. Priority companies who indicated a later date are being contacted to determine their Y2K readiness and to make sure they are on track for meeting their goals. FDA is committed to maximizing the response rate particularly from the 274 priority manufacturers.

Pharmaceutical Audits

Many have urged that FDA take additional actions beyond the survey program that will provide independent assurance of the adequacy of manufacturers' Y2K assessments and any resulting Y2K corrections. As a result, FDA decided to have a contractor, with extensive experience in information

technology and Y2K verification and validation, audit each of the 160 highest priority pharmaceutical firms, as well as a random sampling of other drug manufacturers. The surveys, by the contractor via telephone or on-site interview, were begun on July 19, 1999.

As of October 8, 1999, 88 percent of the assessments have been completed. It is important to note that to date the audit results have confirmed the findings of the survey. These results provide the basis for a clear message to reassure the American public that prescription drugs will continue to be available.

FDA and the pharmaceutical industry will continue to monitor the Y2K status and availability of pharmaceutical supplies. FDA has processes in place to address product availability and has used these procedures to help get necessary products to patients. FDA will continue to work with the health professional community, industry and patient groups regarding Y2K readiness and product availability.

BIOLOGICS INDUSTRY AND Y2K COMPLIANCE

Another section of the pharmaceutical industry produces biological drugs as well as vaccines and blood products. We took the same survey/audit approach with these manufacturers as well.

Survey of Biologics Manufacturers for Y2K Manufacturing Processes

On June 30, 1999, a survey was mailed to 1,576 licensed biologics manufacturers and registered blood establishments. Letters to the biologics trade organizations requesting their assistance in encouraging participation in the survey effort were sent on June 30, 1999. Of the responses that have been received, 92 percent report that they will be Y2K ready by the end of October.

As of October 15, 1999, we have received responses from 1,483 or 94 percent of the firms. Highest priority has been placed on 110 priority firms, which include licensed manufacturers of vaccines, therapeutics, allergenic products, viral marker test kits and major blood organizations. As of October 15, 1999, 101 or 90 percent of the high priority firms have responded.

Biologics Audits

Telephone/site visit audits of these 110 high priority firms began in late August and as of October 14, 1999, audits have been completed for 83 or 75 percent of the high priority firms. To date, we have no reports of problems regarding firms that have been audited. We also have begun audits of a random sample of the firms that are not in the high priority group. As of October 14, 1999, we have completed audits of 48 of these firms with no problems identified.

CONSUMABLE MEDICAL SUPPLY INDUSTRY AND Y2K COMPLIANCE

Survey of Manufacturers of Consumable Medical Supplies for Y2K Manufacturing and Distribution Processes

On June 18, 1999, surveys were mailed to 3,070 consumable medical supplies manufacturers (approximately 2,000 domestic, 1,000 foreign). The focus of the survey is on those manufacturers that produce essential medical devices that are used and consumed on a recurring basis during the delivery of essential healthcare services and whose availability is critical to the uninterrupted delivery of health care and patient welfare. The survey requests information on mission critical automated manufacturing and distribution systems rather than Y2K status information on specific products. A follow-up letter was sent to non-respondents on July 23, 1999. As of October 14, 1999, 2,074 responses and/or returned mail have been received with approximately 90 percent of the fully analyzed responses (1309) reporting Y2K readiness by October 31.

Consumable Medical Supplies Audits

For a sample of survey respondents, validation of survey responses by the contractor via telephone or on-site interview is being conducted. Highest priority for these assessments will be the 225 manufacturers that produce a device only manufactured by 3 or fewer firms, so called "few sources" devices, and the 57 manufacturers that are the sole source for a supply (the 57 manufacturers are included in the 225). Of the 225 "few sources" firms, 197 have responded, and of the 57 sole source firms, 48 have responded. Attention also will be focused on those manufacturers with inconsistent responses. As of October 14, 1999, approximately 58 percent of the assessments of the priority firms have been completed with no serious problems reported. Eighty-nine percent report that they will be Y2K ready by the end of November. It is important to note that the initial audit results confirm the survey results. We will continue to follow-up with those manufacturers that are not Y2K ready and whose supplies, if not available, could have a significant impact on health care delivery.

RECENT AGENCY WIDE OUTREACH EFFORTS

The FDA website, including the Federal Y2K Biomedical Equipment Clearinghouse database, provides much of the information needed by healthcare providers and consumers regarding Y2K and FDA-regulated products. For answers to questions that can not be found on the Y2K website, FDA recently established a Y2K telephone hotline which can be reached by calling FDA's main information line toll-free at 1-888-INFO-FDA or using the Y2K e-mail form on the FDA Y2K website.

FDA also has developed an extensive outreach initiative that will provide video and audio news releases, brochures and articles designed to address the concerns of the consumer and the healthcare community regarding Y2K issues. Additional FDA outreach efforts are noted in the Appendix.

CONCLUSION

In summary, Mr. Chairman, there is now extrinsic and objective evidence that drug and device manufacturers have taken the necessary steps to ensure that their products and production facilities are ready for Year 2000 conversion. Indeed, I believe that manufacturers, wholesalers, and retailers of these products should be commended for taking this issue seriously and for devoting the necessary

resources to protect their customers and, ultimately, patients from Y2K related failures. For those few firms that have not taken these steps, FDA will be vigilant in following up on any reports.

FDA will continue to work with other Federal agencies, patient groups, healthcare provider associations and industry to optimize data collection and information sharing. Together we can provide the American public with the needed assurances that manufacturers will be Y2K ready. We all share a common goal of having medical devices that will function as intended and a safe and adequate drug supply available for the American public as we continue through the year-end transition.

Thank you for the opportunity to testify.

Appendix

Letters to Medical Device Industry

1997

- June 25, 1997, notice to all medical device manufacturers (8,322 domestic and 5,085 foreign) registered with FDA's Center for Devices and Radiological Health (CDRH) indicating that they needed to address this issue and review both embedded and non-embedded software products.

1998

- January 21, 1998, letter which was sent by DHHS to approximately 16,000 medical device and biomedical equipment manufacturers to ask them to voluntarily provide information on the Year 2000 compliance status of their products.
- June 29, 1998, targeted, follow-up letter to specific manufacturers of potentially vulnerable computerized devices.
- September 2, 1998, follow-up to the June 29, 1998, letter directed to the manufacturers of potentially computerized devices who had not responded to the previous requests.
- August 14, 1998 and September 2, 1998, letters from Dr. Bruce Burlington, then Director, CDRH, and Dr. Friedman, then Acting Commissioner of the Food and Drug Administration, to the Health Industry Manufacturers Association (HIMA) requesting that the Association take aggressive and immediate actions to encourage and assist medical device equipment manufacturers in providing information to FDA.
- Late September 1998, FDA posted on the website those manufacturers of selected product categories that are likely to include vulnerable products that had not provided a response to FDA's inquiries.

1999

- March 3, 1999, letter requesting that the 2,300 targeted biomedical equipment manufacturers carefully review the Year 2000 status information that they have provided or intended to submit, and, where necessary, provide more specific information on non-compliant products.

- March 29, 1999, letter requesting that targeted medical device manufacturers submit a complete list of individual product models that are Year 2000 compliant. Responses from 572 manufacturers have been received as of June 1, 1999.
- July 16, 1999, Public Health Notification regarding date-related computer controlled medical devices to administrators, risk managers and biomedical/clinical engineers of 67,000 hospitals and healthcare facilities. The notification urged them to develop contingency and remediation plans to avoid serious adverse events; provided information to assist them in contingency planning; provided information about the Federal Y2K Biomedical Equipment Clearinghouse website; and, encouraged them to report problems or adverse events associated with Y2K and computer-controlled devices to FDA's MedWatch Program.

Additional Outreach and Guidance

In an effort to reach the widest group of individuals, both to get information and to spread information, CDRH also has been conducting extensive outreach to the device industry and to other consumers on this issue. These efforts are as follows:

- CDRH's Division of Small Manufacturers Assistance provided an article in May 1998 entitled "Biomedical Equipment Manufacturers Urged to Share Year 2000 Information" to 12 medical device trade press contacts and to 65 U.S. and 35 foreign medical device trade associations in order to facilitate the dissemination of information to their members regarding the website database and to encourage the posting of data by manufacturers.
- The website and database were mentioned in the FDA Column of the June 3, 1998, *Journal of the American Medical Association* and in an article in FDA's Medical Bulletin that was sent to approximately 700,000 healthcare practitioners this past summer.
- In the spring of 1998, CDRH developed a Guidance Document on FDA's expectations of medical device manufacturers concerning the Year 2000 date problem. The guidance is available on the FDA website.
- FDA also developed an article addressed to the users of radiation treatment planning systems regarding the need to assess these systems. The article was published in the newsletters of relevant professional associations.
- Staff of CDRH have participated in numerous conferences and video teleconferences devoted to the Year 2000 problem in healthcare in order to communicate with healthcare facilities regarding the Biomedical Equipment Clearinghouse and the need to address the Year 2000 issue with devices.
- March 29, 1999, memorandum issued by the Director, Division of Emergency and Investigational Operations, Office of Regulatory Affairs (ORA), to the FDA field instructing investigators to expand the Year 2000 activities to include asking questions regarding what the firm has done to assure that the computer controlled and date-sensitive products, manufacturing processes and distribution systems are Year 2000 compliant.

- On May 17, 1999, the President's Council on Year 2000 Conversion in conjunction with the Veterans Health Administration hosted a Roundtable event. The discussion focused on those services and supply chains that are critical to the health and well-being of all Americans, and in particular the ready availability of pharmaceuticals from their manufacture to the filling of prescriptions at the drug store. The consensus of those present at the Roundtable (the brand name and generic drug manufacturers, wholesalers, and health care providers, payers, along with consumer advocates and government regulators) is that allowing patients to obtain a substantial advance (buying or stockpiling) is not necessary and may actually cause the shortage that this kind of action is trying to prevent. FDA continues to work with the pharmaceutical industry, associations, and other Federal agencies to assure a safe and adequate pharmaceutical supply.
- In a letter to providers, Health Care Financing Administration (HCFA) noted the FDA website for providers to obtain information on medical devices and Y2K compliance status information.
- FDA has participated in 18 national and regional HCFA conferences and three National Association of Rural Health Clinics regional conferences which included discussions of FDA's Y2K activities, status of the Federal Y2K Biomedical Equipment Clearinghouse, pharmaceutical supply issues and future Agency activities.
- On April 16, 1999, a Guidance for Industry and the Clinical Community on "Medical Device Reporting for Date-Related Problems Including Y2K."
- On June 7, 1999, FDA participated in a President's Council on Year 2000 Conversion Roundtable event on medical supplies.
- On August 18, 1999, FDA staff participated in a Health Resources and Services Administration (HRSA) teleconference entitled "Making Your Health Facility Y2K Compliant" directed to HRSA funded rural health clinics.
- On August 24, 1999, FDA issued a Talk Paper entitled "The Year 2000 Date Problem and Medical Devices."

Although most devices are regulated by CDRH, FDA's Center for Biologics Evaluation and Research (CBER) regulates blood bank software, which is of particular concern for potential Year 2000 problems. In January 1998, CBER posted guidance for industry entitled "A Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products" on the FDA website. The guidance provided specific recommendations to assist industry in its evaluation of computer and software systems used in the manufacture of blood products and to assist in evaluating the impact of potential Year 2000 problems. CBER is aware of the status of these individual products and believes that the blood bank software will be Y2K compliant or will have a "patch" or "work-around" for the systems to ensure that the systems will work through Year 2000.

STATEMENT BY
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DEPARTMENT OF VETERANS AFFAIRS

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

October 28, 1999

Introduction

It is my pleasure to testify on behalf of the Department of Veterans Affairs (VA) on the status of our readiness for the Year 2000. I am accompanied today by Harold Gracey, VA's Acting Chief Information Officer (CIO), and other key staff from VA's Office of Information and Technology, the Veterans Benefits Administration (VBA), the Veterans Health Administration (VHA), and the National Cemetery Administration (NCA) who have been involved in Year 2000 full-time for the last several years.

We have worked very hard in VA to ensure that we will be ready for the Year 2000. We have program delivery people and information technology people working hand-in-hand across VA to ensure that we provide uninterrupted support of benefits delivery and health care services.

I appear before you today to say I remain confident that benefit payments will be made without interruption, and our health care facilities will be operational on January 1, 2000. Veterans will continue to receive their benefits on time, as well as the highest quality of health care in the Year 2000 and beyond.

Since the last hearing VA has conducted a number of post-implementation tests to provide added assurance that our systems will operate properly in the Year 2000. VA has utilized Year 2000 simulated date environments, complete with third-party compliant software and hardware, to simulate system activity during the century transition and in the Year 2000 and beyond.

One major accomplishment was the successful completion of a business process simulation (BPS), conducted from July 3 - 6, 1999. During these tests, VA systems internal date settings were advanced to January 2000, including veteran data, software applications, communications and computer platforms. Benefits and health care transactions were processed in order to simulate normal business activities in the Year 2000. Over $3.5 billion dollars in benefit payments were successfully processed in the simulated January 2000 payment

cycles. Over 125 VA personnel participated in this test. *No Year 2000 problems were encountered* during the simulation

VA has also conducted additional post-implementation tests. Previously, in April 1999, VA's Office of Financial Management performed a series of tests to verify that the various systems involved in issuing payments to vendors and employees will work together properly in the Year 2000. In addition, in August 1999, VHA's *VISTA* integrated suite of applications was tested in a simulated forward-dated hospital environment to simulate normal medical center activity in the Year 2000. *VISTA* is the name given to the standardized set of national software applications that form the automated systems environment supporting integrated health care delivery at local VA health care facilities.

Business Continuity and Contingency Plans

Although VA has made its systems Year 2000 compliant, there remains a dependency upon products and services provided by third parties (such as water and electricity companies). VA has developed Business Continuity and Contingency Plans (BCCPs) to minimize Year 2000 impacts on its core business functions.

In the event of any problems external to the Department, VA has classified its core business functions into two critical areas: health care (VHA) and benefits delivery (VBA). The BCCP for benefits delivery, including benefit payments, was completed in January 1999. The *Patient-Focused Year 2000 Contingency Planning Guidebook,* VHA's BCCP, was completed in March 1999.

VA's regional offices and health care facilities were provided these plans and templates so that they could customize their individual plans according to their local needs. The customized extensions for VA's three data processing centers, 58 regional offices, and 172 health care facilities were completed in May 1999. VA health care facilities include hospitals, outpatient clinics, domiciliaries, and nursing homes, all of which have been included in local level BCCPs. These BCCPs will greatly mitigate the potential impacts on the delivery of benefits and health care by entities outside VA's control.

Day One Planning

Our focus in the remaining days until the actual date rollover is making pre-rollover, rollover and post-rollover plans, commonly referred to as Day One Plans. VA has developed Day One Plans that identify comprehensive sets of actions to be executed during the last days of 1999 and the first days of 2000. The Day One Plans are designed to minimize any adverse impact on operations and key business processes, help protect data, applications and equipment, and improve the ability to recover should Year 2000 related problems be encountered. In addition, the Day One Plans are a mechanism for monitoring

and reporting VA's Year 2000 experience to VA executive management, the President's Council on Year 2000 Information Coordination Center (ICC), veterans and their families.

VA has developed a *Day One Strategy Overview* that provides a high level summary of VA's strategy to manage and mitigate the risks of potential Year 2000 related disruptions to agency operations. I would be happy to provide a copy for the record.

Because VA's work supporting health care and benefits delivery is normally conducted at the local level nationwide, the authority to solve rollover problems has been delegated locally to the health care facilities, and to the regional offices. Local facilities and regional offices have the authority to execute appropriate contingencies, if they determine that a situation exists that requires the execution of the BCCP.

VA's recent focus has been the review and validation of our BCCPs at our local facilities. VHA has been performing a series of BCCP site visits to ensure the quality of BCCPs and preparations for Day One. Similarly, VBA has reviewed regional office BCCPs and Day One Plans. In addition to internal reviews, GAO, using on-site visits and document reviews, has reviewed many of VA's health care facilities and regional office BCCPs. VA's Office of the Inspector General has also completed a written survey of all VA facilities, and has performed selected site reviews at VA health care facilities and regional offices.

As described in my April 15, 1999, testimony, it is important to point out two mitigation and preparatory activities that VA has completed or plans in order to help minimize potential Year 2000 disruptions to benefits and health care delivery – the date of benefit payments and the performance of emergency power drills.

Date of Benefit Payments

Most of the regular, recurring benefit payments, including Compensation and Pension, Education Chapters 32, 35, 1606, Vocational Rehabilitation, REPS, and spina bifida will be posted, as they normally would have been, to the beneficiaries' accounts and will be available on the morning of December 30, 1999. This will greatly mitigate possible Year 2000 interruptions of benefit payments.

Conduct of Emergency Power Drills

Each VHA facility has performed an emergency power drill to prepare for various power disruption scenarios. Each facility, under controlled conditions to prevent any harm to patients, supplied facility electrical power using the emergency generator system after disconnecting from the local electrical power supply for

up to eight hours. This drill demonstrated that health care facilities could operate under emergency power, if necessary. Drills were completed by August 1999.

Department of Treasury Testing and Payment Contingencies

In May 1999, VBA conducted extensive Year 2000 testing that culminated with the transfer of payment files to the Department of the Treasury. During this testing, over 35 payment files representing over $3.5 billion dollars were transmitted to the Treasury. The Treasury informed us that these payments were processed correctly. The Treasury then tested the Compensation and Pension (C&P) files with the Federal Reserve and 40 million C&P Electronic Fund Transfer payments were successfully processed. In addition, Treasury successfully tested its ability to process and issue paper checks currently made to beneficiaries.

In addition, we have several contingencies in place with Treasury in the unlikely event of a problem. In fact, an entire subset of our BCCP for benefits delivery deals with Treasury issues to ensure that beneficiaries will receive their benefit payments on time and correctly when the new century begins. These plans include a worst case scenario in which the private banking electronic systems fail or have problems. If this occurs, Treasury can revert to the use of paper checks to deliver veterans payments after recertification of those payments by VA. In addition, if the VA systems cannot process payments in January 2000, we will provide a contingency payment file for Treasury's use so that they can generate veterans' payments. We feel these are unlikely events, but we are ready with contingencies in case they are needed.

Based on the fact that both VA and FMS and the Federal Reserve System are already Year 2000 ready, and that we have thoroughly conducted post-implementation testing, I am confident that all benefit payments will be made without interruption in the Year 2000 and beyond.

Medical Devices

The potential Year 2000 impact on medical devices is a national issue, affecting both private sector and Federal health care communities. VA, like any other health care provider, buys these devices from private industry. The Food and Drug Administration (FDA) regulates these products.

Medical Device Status

Approximately two years ago, VHA identified about 1600 vendors from which the medical facilities have procured medical devices. This number was reduced to 1379 through research, discussion with medical engineers at VAMCs, and contact with vendors/distributors. Distributors and manufacturers that do not

produce biomedical devices were removed from the database. To date, we have received responses from more than 99% of the manufacturers.

VHA estimates that over 96% of the devices provided by these manufacturers that we use are compliant, about 3% are conditionally compliant (meaning a fix or upgrade will be provided by the manufacturer) and less than 1% are non-compliant.

Consolidated Mail Outpatient Pharmacy (CMOP)

The Consolidated Mail Outpatient Pharmacy (CMOP) is a regional system composed of seven facilities that is used to expedite the processing and distribution of mail-out prescriptions to veterans. More than 50% of VHA prescriptions are filled by the CMOPs.

As of September 30, 1999, VHA had completed the Year 2000 repairs and testing of the seven CMOPs. The renovation strategy consisted of the repair of non-compliant systems as well as the implementation of new systems. Two of the seven CMOPs are now running new non-proprietary, state-of-the-art software that operates on a more user-friendly, fully compliant platform and thus are capable of filling a higher volume of prescriptions. All the CMOPs renovation work was performed without compromising the filling and distribution of prescriptions to veterans.

As part of the VHA Year 2000 project, the CMOPs have developed Year 2000 contingency plans to supplement their existing National Disaster and Recovery plans. The CMOPs have also tested all the hardware, software interfaces, and contingency plans with the medical facilities. The contingency plans address the pharmaceutical supply chain, and the readiness of pharmaceutical manufacturers, utility companies, and other suppliers the CMOPs depend on for their operation.

The CMOPs are fully Year 2000 compliant and we are confident there will be no interruption in filling prescriptions for veterans into the next century.

Moratorium

VA has established a nationwide moratorium on the implementation of new systems, changes to existing systems or third-party upgrades between October 15, 1999 and March 31, 2000. Our goal is to ensure that we do not introduce Year 2000 vulnerabilities or defects into our Year 2000 certified systems. The only exclusions to the moratorium are changes to correct Year 2000 related problems, repairs for other production problems, cost-of-living adjustments, and changes required by legislative mandates. This nationwide moratorium ensures that our information technology environment will remain stable during the rollover to the next millennium and beyond. It is necessary to ensure that VA will

continue to provide uninterrupted services to veterans and the communities that we serve.

Summary

VA has made its systems supporting health care and benefits delivery Year 2000 compliant. VA has completed successfully the necessary testing for both the veterans' benefits and high impact health care programs, and we feel confident that these programs are ready for the Year 2000 and beyond. VA also has completed BCCPs to provide for uninterrupted health care and benefits delivery.

VA is making preparations for the upcoming Year 2000 date rollover to ensure benefit payments will be made without interruption and that VA health care facilities will be operational on January 1, 2000 and beyond. Our Nation's veterans and their families will continue to receive their benefits on time, as well as the highest quality of health care. I thank you for this opportunity to present our progress in preparing for the Year 2000. I would be happy to answer any questions you have.

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